

1 FEDERAL TRADE COMMISSION

2 I N D E X (PUBLIC RECORD)

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4 WITNESS: DIRECT V-DIRE CROSS REDIRECT RECROSS

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8 EXHIBITS FOR ID IN EVID

9 Commission

10 Number 508 7538

11 Number 518 7513

12 Number 519 7520

13 Number 532 7517

14 Number 536 7518

15 Number 769 7530

16 Schering

17 Number 34 7565

18 Upsher

19 None

20

21 OTHER EXHIBITS REFERENCED PAGE

22 Commission

23 CX 507 7540

24 CX 523 7577

25 CX 525 7583

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1	Schering	
2	SPX 112	7550
3	Upsher	
4	USX 7	7584
5	USX 21	7503
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FEDERAL TRADE COMMISSION

In the Matter of:)
SCHERING-PLOUGH CORPORATION,)
a corporation,)
and)
UPSHER-SMITH LABORATORIES,) File No. D09297
a corporation,)
and)
AMERICAN HOME PRODUCTS,)
a corporation.)
-----)

Wednesday, March 13, 2002

1:00 p.m.

TRIAL VOLUME 31

PART 1

PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL

Administrative Law Judge

Federal Trade Commission

600 Pennsylvania Avenue, N.W.

Washington, D.C.

Reported by: Susanne Bergling, RMR

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1 P R O C E E D I N G S

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3 JUDGE CHAPPELL: Ms. Shores? Let's reconvene
4 docket 9297.

5 MS. SHORES: Thank you, Your Honor.

6 We have a matter of documents to be raised. As
7 you might recall, at the end of last week, we had
8 mentioned we were still trying to work out our
9 differences. To a significant degree, we have worked
10 out our differences, and we will be submitting a joint
11 stipulation by the end of court today, which I believe
12 will be JX-5, as to certain documents.

13 There are some documents that we have not been
14 able to work out our differences, and I think
15 unfortunately we're going to have to take a little bit
16 of the Court's time to deal with those. They are 35
17 documents, Your Honor, they fall -- 35 exhibits,
18 rather, and they fall within the category of patent
19 documents from the underlying patent cases. They
20 consist of interrogatories and answers to
21 interrogatories, motions for summary judgment and
22 exhibits thereto, and --

23 JUDGE CHAPPELL: Why don't we take that up
24 after the witness finishes today.

25 MS. SHORES: That's fine. Your Honor. I

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1 didn't want as a technical matter to not get it in
2 before we rested, but if you want to take it up later,
3 that's fine.

4 JUDGE CHAPPELL: Okay. Anything else?

5 MR. CURRAN: Your Honor, we have similar
6 issues, but we can wait until after the witness if it's
7 Your Honor's desire to hear the witness before we rest.

8 JUDGE CHAPPELL: Right, let's do that.

9 MR. CURRAN: Thank you, Your Honor.

10 JUDGE CHAPPELL: Okay, I'm prepared to rule on
11 complaint counsel's motion for leave to call William
12 Groth or Groth, G R O T H, as a rebuttal witness.
13 Who's representing complaint counsel on this motion?

14 MR. ORLANS: I do, Your Honor.

15 JUDGE CHAPPELL: Mr. Orlans, I just wanted to
16 confirm that -- do you deny that you questioned Mr.
17 Dritsas about this issue of substitution during his
18 deposition?

19 MR. ORLANS: I'm sorry, do we deny that we
20 questioned him? No, we don't, Judge.

21 JUDGE CHAPPELL: Okay. I have reviewed the
22 pleadings and the oral argument yesterday. I find that
23 this issue was not a surprise, it was not unexpected.
24 Therefore, the Government has not established good
25 cause. The motion for leave to call William Groth as a

1 rebuttal witness is denied.

2 Call your next witness.

3 MR. ORLANS: Your Honor, one point of order in
4 that regard. We would like the opportunity to at least
5 contemplate some sort of a formal proffer so that the
6 record would reflect what the witness' testimony would
7 have been, either by way of declaration or in some
8 other form, but --

9 JUDGE CHAPPELL: Why don't you do it in
10 writing.

11 MR. ORLANS: That's fine, Judge.

12 JUDGE CHAPPELL: And we will make it part of
13 the record, although it's pretty much in the record
14 based on your argument yesterday. Whatever you would
15 like to do, I will accept it into the record.

16 MR. ORLANS: Surely. Thank you, Your Honor.

17 MS. BOKAT: Your Honor, complaint counsel are
18 prepared to call our first rebuttal witness. He will
19 be handled by Ms. Yaa Apori, one of complaint counsel.

20 JUDGE CHAPPELL: Okay, proceed.

21 MS. APORI: Good afternoon, Your Honor. Before
22 we begin, I would like to introduce counsel for Kos
23 Pharmaceuticals, John Campbell.

24 MR. CAMPBELL: Good afternoon, Your Honor.

25 MS. APORI: At this time we call Mr. Mukesh

1 Patel to testify.

2 JUDGE CHAPPELL: Please remain standing and
3 raise your right hand.

4 Whereupon--

5 MUKESH P. PATEL

6 a witness, called for examination, having been first
7 duly sworn, was examined and testified as follows:

8 JUDGE CHAPPELL: State your full name for the
9 record, please.

10 THE WITNESS: Mukesh Prahlad Patel.

11 JUDGE CHAPPELL: Go ahead.

12 DIRECT EXAMINATION

13 BY MS. APORI:

14 Q. Good afternoon, Mr. Patel.

15 A. Good afternoon.

16 Q. Please tell us your educational background.

17 A. I am a pharmacist who trained in the UK, and I
18 have a Master's in medicinal chemistry at a university
19 in the UK.

20 Q. And what university was that?

21 A. At Loughborough University of Technology.

22 Q. Are you currently employed?

23 A. I am.

24 Q. By whom?

25 A. By Otsuka America Pharmaceutical Company.

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1 Q. And what does Otsuka do?

2 A. Otsuka is a Japanese pharmaceutical company,
3 and I work for the U.S. subsidiary of that company.

4 Q. How long have you worked there?

5 A. I joined the company the end of May of last
6 year.

7 Q. And what is your current position?

8 A. I am senior director of business and commercial
9 development.

10 Q. As senior director, what are your duties and
11 responsibilities?

12 A. My responsibilities are -- involve licensing in
13 technology and products, as well as licensing out or
14 partnering out certain technologies and products of
15 ours.

16 Q. Where did you work before joining Otsuka?

17 A. I was at Kos Pharmaceuticals.

18 Q. And during what time period were you employed
19 by Kos?

20 A. From 1991 to March of 2001.

21 Q. And what does Kos do?

22 A. Kos is a U.S. pharmaceutical company.

23 Q. And what positions did you hold while at Kos?

24 A. I started as director of licensing, and in the
25 last two or three years, I was vice president of

1 licensing.

2 Q. As vice president of licensing, what were your
3 duties and responsibilities?

4 A. I would be involved in all negotiations and
5 partnering activities involving our technologies and
6 products as well as seeking technologies and products
7 and partnerships with outside organizations.

8 Q. Did that include negotiating licenses?

9 A. It did.

10 Q. And how many negotiations did you participate
11 in?

12 A. During the time at Kos?

13 Q. Yes.

14 A. Literally hundreds of discussions would start,
15 and a small portion of those would eventually be
16 executed.

17 Q. How many of those negotiations resulted in
18 agreements between Kos and another company?

19 A. About 30 over the course of ten years.

20 Q. And why did you leave Kos?

21 A. I found gainful employment elsewhere, and it
22 offered me some opportunities, including some
23 opportunities for my family.

24 Q. Where did you work before joining Kos?

25 A. I was employed in the UK for Glaxo Companies.

1 Q. And when did you work with Glaxo?

2 A. For the 12 years prior to 1991.

3 Q. What positions did you hold while at Glaxo?

4 A. I started out as a medical information officer
5 and then during the 12 years moved into business
6 development, and the last position I held there was as
7 a representative of the international licensing
8 department for the parent company.

9 Q. And as an international licensing executive,
10 what were your responsibilities?

11 A. It involved meeting companies internationally
12 and seeking various partnerships that would suit the
13 company, either technologies that we had which we would
14 partner on the outside or technologies on the outside
15 that we would want to bring into the company.

16 Q. Now, Mr. Patel, while you were at Kos, what
17 drugs did the company have under development?

18 A. The company had an extended release niacin
19 product that it was developing as well as several other
20 entities in various slow release formulations that we
21 were testing and a number of respiratory delivery
22 products.

23 Q. At the time you left Kos, what stage of
24 development were the respiratory products?

25 MR. CURRAN: Objection, Your Honor. The final

1 witness list of complaint counsel indicates that Mr.
2 Patel will be testifying on two subjects. One, the
3 negotiations between Kos and Schering-Plough regarding
4 Niaspan; and two, issues relating to the marketing of
5 Niaspan in Europe. It appears that the question is
6 straying from those parameters.

7 MS. APORI: Your Honor, I'm attempting to lay a
8 foundation as to the points Mr. Patel would be
9 testifying to if you will allow me a little latitude.

10 JUDGE CHAPPELL: I'm not sure the stage of
11 development of the respiratory products is necessary
12 for a foundation. I'll sustain the objection.

13 BY MS. APORI:

14 Q. Mr. Patel, are you familiar with Niaspan?

15 A. I am.

16 Q. What is it?

17 A. It's an extended release formulation developed
18 by Kos containing niacin as the active ingredient for
19 the treatment of cholesterol disorders.

20 Q. What therapeutic class of drugs does Niaspan
21 belong to?

22 A. It's a cholesterol therapy.

23 Q. Was niacin, the compound, available before
24 Niaspan came onto the market?

25 A. Niacin is an active ingredient available well

1 before we developed our formulation.

2 Q. And in what formulation was niacin available?

3 A. It's available through many manufacturers in
4 immediate release form, slow release form, and it's
5 also an ingredient in a number of over-the-counter
6 vitamin preparations.

7 Q. Mr. Patel, what is the advantage of taking
8 Niaspan instead of immediate release forms of niacin?

9 MR. CURRAN: Objection, Your Honor, it appears
10 to call for expert testimony.

11 JUDGE CHAPPELL: Sustained.

12 MS. APORI: Your Honor, I would offer Mr. Patel
13 was vice president of licensing, and in his duties, he
14 had to sell niacin -- Niaspan and characterize what he
15 felt the advantages of his product were over existing
16 formulations. That's what the question goes to.

17 JUDGE CHAPPELL: I understand, but he wasn't
18 designated to talk about this subject, so the objection
19 is sustained.

20 BY MS. APORI:

21 Q. Mr. Patel, can you describe the process Kos
22 went through to get FDA approval for Niaspan?

23 A. Our formulation of Niaspan was developed as an
24 NDA development and filing, which involved a number of
25 lengthy pharmacokinetic and clinical studies.

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1 MR. CURRAN: Objection, Your Honor. This,
2 again, is straying from the subjects identified. We're
3 getting into what Kos had to do to get NDA approval.
4 That is not something identified as a subject this
5 witness would address in the final witness list.

6 MS. APORI: Your Honor, however, this is a
7 subject that was brought up in the case in chief by
8 respondents. Respondents have raised the issue that
9 niacin is a straightforward drug, did not call for much
10 due diligence or studies. Mr. Patel's testimony will
11 directly rebut that. His testimony directly responds
12 to testimony offered by Mr. Audibert and Mr. Lauda on
13 direct, and I do have cites to their direct testimony
14 if you would like for me to enter that into the record.

15 MR. CURRAN: Your Honor, we would have deposed
16 this witness if we knew he was going to testify beyond
17 the scope of the subjects identified in the witness
18 list.

19 MS. APORI: Your Honor, Mr. Patel has been
20 identified as a witness on complaint counsel's witness
21 list since last fall -- excuse me, since last summer,
22 and they have had an opportunity to depose Mr. Patel
23 and have not exercised that opportunity.

24 JUDGE CHAPPELL: Did you notify them that he
25 would be testifying about the subjects you're going

1 into now?

2 MS. APORI: No, Your Honor, but I would remind
3 you again that this was an area that was brought up for
4 the first time by Mr. Audibert and Mr. Lauda in their
5 direct testimonies and in the respondents' case in
6 chief, and so that was an area that was -- that was
7 focused on more highly during the trial than before the
8 trial, and we brought Mr. Patel to respond to those
9 statements.

10 And Your Honor, we did make this clear in the
11 opposition to the motion to strike Mr. Patel's
12 testimony filed earlier this week.

13 MR. CURRAN: Two points in response to that,
14 Your Honor. Point one, again, the real issue here is
15 whether or not we had notice as to what this witness
16 was going to testify about in order to make an informed
17 decision as to whether to take his deposition or not.
18 Ms. Apori, I believe, has already conceded that this
19 witness was not identified as one to testify about
20 pharmacokinetic studies.

21 Secondly, pharmacokinetic studies were not
22 raised by respondents in their case in chief. You will
23 recall Dr. Levy testified about pharmacokinetic studies
24 and said they were like falling off a log.

25 MS. APORI: Your Honor, Dr. Levy's testimony

1 was specifically referring to I believe Schering, and
2 Mr. Audibert and Mr. Lauda's testimony in respondents'
3 case in chief talked about how pharmacokinetic studies
4 or additional study into niacin is straightforward,
5 easy to complete and not -- not time-intensive.

6 Mr. Patel, as an executive at Kos who oversaw
7 the development of Niaspan and also shopped Niaspan
8 around, can speak to the extensive pharmacokinetic
9 studies and the long and difficult process that Kos had
10 to undergo to have Niaspan approved. This is an area
11 that was made more prominent by the defense in their
12 case and not raised as prominently earlier. So, we are
13 responding to the -- to the issue that they put into
14 the record.

15 MR. NIELDS: Your Honor, I've remained silent,
16 but I would like to make two quick points on behalf of
17 Schering.

18 The first has been already made, and that is
19 it's very clear that in the witness list and the
20 statement of complaint counsel as to what Mr. Patel
21 would testify about, this is not in there at all, and
22 Ms. Apori has conceded that.

23 Second, there was no testimony by Schering or
24 anyone else in this case about the approval process for
25 Niaspan, never been raised. This is inappropriate

1 rebuttal.

2 MS. APORI: Your Honor, I would counter that it
3 is fair rebuttal, and I draw your attention to the
4 direct testimony of Mr. Lauda specifically at
5 transcript page 4347, lines 1 through 23, and again to
6 the testimony of Mr. Audibert, and during that time --
7 if you will allow me, I will read that into the record.

8 JUDGE CHAPPELL: Just summarize it for me,
9 please.

10 MS. APORI: The summarization was that
11 niacin -- that pharmacokinetic studies were easy to
12 complete, that niacin was a straightforward drug, and
13 that -- and that was repeated by not only Mr. Lauda but
14 also by Mr. Audibert, and that is why Mr. Patel will be
15 testifying as to those issues.

16 JUDGE CHAPPELL: Okay, and you're telling me
17 that the first time complaint counsel heard about
18 pharmacokinetic studies was during respondents' case?

19 MS. APORI: No, Your Honor, that's not what I'm
20 alleging. There were lots of explanations and
21 arguments offered by the defense during pretrial
22 discovery. We did not have an opportunity to learn
23 which -- which specific arguments would be put into
24 issue or emphasized, though, by the defense until they
25 put on their case in chief. At that point, we feel

1 that we should be allowed to have -- to respond to the
2 statements that they've made.

3 JUDGE CHAPPELL: Well, I am going to overrule
4 the objection, but I am only going to allow you to ask
5 him whether or not studies were done. He's not an
6 expert. He's not going to tell us what they are, what
7 they're about. So, you're going to have a limited
8 range of questioning here.

9 MS. APORI: Okay.

10 BY MS. APORI:

11 Q. Mr. Patel --

12 May I approach the witness, Your Honor? I'd
13 like to present him and respondents with some documents
14 to be covered during the direct.

15 JUDGE CHAPPELL: Yes, you may.

16 BY MS. APORI:

17 Q. Mr. Patel, I ask you to turn to what's been
18 marked USX 21 and has been previously admitted.

19 Have you ever seen this document?

20 A. Yes, I have.

21 Q. And what is it?

22 A. It is the Kos Pharmaceuticals registration
23 statement when the company went public.

24 Q. I ask you to turn to the Bates number AAA
25 0000078, also known as page 27 of USX 21.

1 Your Honor, I have just been informed that the
2 computers aren't working on complaint counsel's side,
3 if we can arrange for them --

4 MR. SILBER: Your Honor, we are just trying to
5 make sure the documents are displayed for you and
6 respondents' counsel. We are just trying to get
7 through this glitch.

8 JUDGE CHAPPELL: Well, let's just pause while
9 you see if the cables will work here.

10 (Pause in the proceedings.)

11 MR. SILBER: I think we're okay now. Thank
12 you, Your Honor.

13 JUDGE CHAPPELL: Okay, let's proceed.

14 BY MS. APORI:

15 Q. Mr. Patel, let's take a look at the box on page
16 27. How many pharmacokinetic studies did Kos complete?

17 A. Fourteen pharmacokinetic studies are listed
18 here.

19 Q. And did the FDA scrutinize the results of these
20 studies?

21 A. They did.

22 Q. Was Kos required to redo any of these studies?

23 MR. CURRAN: Objection, Your Honor, on the same
24 grounds I've raised before. If this witness is being
25 proffered to rebut testimony about the PK studies done

1 on Niacor-SR, I'd like to take some voir dire of the
2 witness to establish that there's no foundation.

3 JUDGE CHAPPELL: Go ahead.

4 VOIR DIRE EXAMINATION

5 BY MR. CURRAN:

6 Q. Mr. Patel, I'm Christopher Curran representing
7 Upsher-Smith.

8 Sir, you're not familiar with what PK studies,
9 if any, were done in connection with Niacor-SR,
10 Upsher-Smith's sustained release niacin product,
11 correct?

12 A. That's correct.

13 Q. In fact, you're not aware of the clinical
14 studies at all done in connection with Niacor-SR,
15 correct?

16 A. That's correct.

17 Q. And you're not aware of what the discussions
18 were regarding PK studies when Kos -- when Upsher-Smith
19 and Schering-Plough were negotiating their deal,
20 correct?

21 A. That's correct.

22 Q. The only PK studies that you're familiar with
23 and prepared to testify about today are those relating
24 to Niaspan, correct?

25 A. That's right.

1 Q. So, you concede, then, that you have no
2 knowledge of PK studies conducted in connection with
3 Niacor-SR, correct?

4 A. That's right.

5 MR. CURRAN: Thank you, Your Honor.

6 MS. APORI: Your Honor, before we proceed, I
7 just direct your attention again back to the statements
8 made by defense -- defendants' witnesses Lauda and
9 Audibert. They speak generally to niacin, niacin the
10 compound, not specifically to Niacor-SR. We are asking
11 to -- for -- we are asking for Mr. Patel to generally
12 speak to Niaspan, an example of a niacin compound, so
13 that he can -- we can get a sense of the difficulties
14 involved in getting approval for a sustained release
15 niacin drug.

16 MR. NIELDS: Your Honor, I would object to that
17 on the ground that it turns this witness into an
18 expert. If he wants to testify as to facts about
19 Niaspan, assuming they're relevant, that's one thing,
20 but now she's turning him into an expert on niacin.

21 JUDGE CHAPPELL: Sustained. He's not an expert
22 witness, Ms. Apori.

23 MS. APORI: Your Honor, if I may, I am again
24 just focusing on specifically the studies as related to
25 Niaspan, the compound. They are used to rebut the

1 statements of defendants' fact witnesses on niacin.

2 JUDGE CHAPPELL: You can ask him what he saw
3 and what he knows, that's all.

4 MS. APORI: Okay.

5 DIRECT EXAMINATION (cont)

6 BY MS. APORI:

7 Q. Was Kos required to redo any of these
8 pharmacokinetic studies?

9 MR. CURRAN: Objection. Isn't that the
10 question that I objected to and you just sustained,
11 Your Honor?

12 JUDGE CHAPPELL: I'll allow him to answer that.

13 THE WITNESS: Could you repeat the question,
14 please?

15 BY MS. APORI:

16 Q. Sure, Mr. Patel.

17 Was Kos required to redo any of the
18 pharmacokinetic studies for Niaspan?

19 A. I believe some additional studies were required
20 on pharmacokinetics for Niaspan as a result of
21 discussions in years prior to approval.

22 Q. How many NDAs did Kos file to -- for approval
23 of Niaspan?

24 A. Kos filed an NDA two or three years prior to
25 the filing that resulted in the approval in 1997.

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1 Q. Why was it necessary to file -- refile the NDA
2 for Niaspan?

3 A. Because some additional studies were required
4 in preclinical and in clinical development of Niaspan.

5 Q. Was the drug ultimately approved in 1997?

6 A. It was.

7 Q. Where did Kos plan to introduce Niaspan first?

8 A. In the U.S.

9 Q. Why?

10 A. That was the market with the largest potential
11 in our opinion. It was the area that we had
12 concentrated our development and regulatory approval
13 activities.

14 Q. And what was the perception of niacin as a
15 cholesterol-fighting drug from the companies that you
16 attempted to license Niaspan to?

17 MR. NIELDS: Objection, hearsay.

18 MS. APORI: Your Honor, in his search for a
19 co-promoting partner for Niaspan, he did have an
20 opportunity to speak to many companies, but he did
21 become personally aware of aspects of niacin, its
22 perceptions within the market.

23 JUDGE CHAPPELL: Are you offering it for the
24 truth?

25 MS. APORI: I'm offering it for -- to show that

1 he has had an opportunity to speak with these and there
2 was communicated to him various perceptions about
3 Niaspan which he became aware of.

4 JUDGE CHAPPELL: So, you are not offering it
5 for the fact of whether the perceptions are true but
6 the fact that --

7 MS. APORI: No, I am not offering it for its
8 truth, Your Honor.

9 MR. CURRAN: Given that statement, Your Honor,
10 I object on grounds of relevance.

11 JUDGE CHAPPELL: How is it relevant?

12 MS. APORI: Your Honor, it's relevant to show
13 that Mr. Patel's awareness of the perceptions of
14 Niaspan had an impact on how the product was shopped
15 around to various companies, specifically, the
16 relevance to setting up a foundation as to how he would
17 respond to the Schering-Kos negotiations, how it was
18 shopped to Schering.

19 JUDGE CHAPPELL: I'll allow it. Overruled.

20 BY MS. APORI:

21 Q. Mr. Patel, what was the perception of niacin as
22 a cholesterol-fighting drug from the companies that you
23 attempted to license Niaspan to?

24 MR. NIELDS: Your Honor, I apologize for
25 interrupting, but I object to the degree that he's

1 going to respond based on conversations after his
2 conversations with Schering. She's announced a theory
3 of relevance that has to do with his state of mind at
4 the time of the negotiations with Schering. So, I
5 would have no objection to his answering based on
6 conversations before the Schering negotiation.

7 JUDGE CHAPPELL: Are you going to limit it to
8 that?

9 MS. APORI: Oh, yes, Mr. -- I think we can
10 establish that Mr. Patel's knowledge will be from his
11 general knowledge as a VP of licensing and his
12 experiences throughout the development of Niaspan, not
13 only his experiences after his discussions with
14 Schering.

15 JUDGE CHAPPELL: But you're asking up to the
16 point that -- a point in time that ends with the
17 discussions with Schering?

18 MS. APORI: I'll redirect the question to that
19 point, um-hum.

20 JUDGE CHAPPELL: Thank you.

21 BY MS. APORI:

22 Q. Mr. Patel, prior to your discussions with
23 Schering in 1997, what was the perception of niacin as
24 a cholesterol-fighting drug from the companies you
25 attempted to license Niaspan to?

1 A. All companies recognized the efficacy of the
2 active ingredient, niacin, but the special matter that
3 they needed to recognize and did recognize was that our
4 formulation was not only efficacious but also safe with
5 respect to certain activities on the body, and that was
6 tied to our formulation.

7 Q. And can you describe again what the
8 formulation -- the special formulation of Niaspan is?

9 A. Our formulation alleviated flushing compared to
10 other niacin products. Our formulation had minimal to
11 no effects on the liver compared to other niacin
12 products. That was the crux of our development
13 program.

14 Q. Mr. Patel, in your position at Kos, did your
15 responsibilities include searching for a partner to
16 co-promote Niaspan?

17 A. It did.

18 Q. At some point, did Kos and Schering enter into
19 discussions about Kos' Niaspan product?

20 A. We did a few times.

21 Q. When did that first occur?

22 A. Our first discussions occurred in years between
23 '92 and '94, and I don't recall exactly when those
24 discussions occurred.

25 Q. What was the outcome of those discussions?

1 A. Our product at the time was in an early stage
2 of development, and at that time it was decided that we
3 wouldn't discuss an actual partnership.

4 Q. Did the possibility of working with Schering on
5 Niaspan come up again?

6 A. It did.

7 Q. And when was that?

8 A. In the 1997 time frame.

9 Q. What prompted the renewed discussions between
10 Schering and Kos?

11 A. The senior management of Kos, namely the
12 chairman and the CEO, had discussions with senior
13 management at Schering-Plough, and it was decided and
14 agreed to look into the project now that it had
15 advanced further.

16 Q. Can you identify which Kos employees
17 participated in the negotiations with Schering?

18 A. The negotiations involved myself, Dan Bell and
19 David Heatherman. There were meetings which I wouldn't
20 say were negotiations but exchange of information on
21 marketing and development, and on that matter a few
22 others at Kos were also involved.

23 Q. At this time, Mr. Patel, I'd ask you to turn to
24 CX 518 in your binder. Do you recognize this document?

25 A. I do.

1 Q. What is this document?

2 A. This is just a note internally from me to Dan
3 Bell, the CEO.

4 Q. And did you prepare this note?

5 A. I did.

6 Q. Looking at the right-hand side of the page, is
7 that your handwriting?

8 A. It is.

9 Q. CX 518 is dated January 17th, 1997. Did you
10 prepare that at about that time?

11 A. I did.

12 Q. And did you prepare it in the ordinary course
13 of business?

14 A. I did.

15 MS. APORI: At this time, Your Honor, I offer
16 CX 518 into evidence.

17 MR. NIELDS: No objection, Your Honor.

18 MR. CURRAN: No objection from Upsher, Your
19 Honor.

20 BY MS. APORI:

21 Q. Looking at --

22 JUDGE CHAPPELL: Would you like me to rule?

23 MS. APORI: I apologize.

24 JUDGE CHAPPELL: CX 518 is admitted.

25 (Commission Exhibit Number 518 was admitted

1 into evidence.)

2 BY MS. APORI:

3 Q. Looking at the top of the page, who is "Dan"?

4 A. "Dan" is Dan Bell, the CEO of Kos.

5 Q. And can you describe the conversation that's
6 discussed in this exhibit?

7 A. This is a conversation that I had with the
8 business development licensing person at Schering where
9 we had discussed opening up some cooperation
10 possibilities on Niaspan.

11 Q. Who is Karin Gast?

12 A. I believe she represents Schering's business
13 development licensing activities.

14 Q. I direct your attention to the handwriting on
15 the right-hand side of the page. What do those notes
16 refer to?

17 A. These notes refer to the conversation Dan and I
18 had once he had read this note, which describes the
19 conversation I had had with Schering. So, it talks
20 about the origins of what sparked this discussion off
21 and that Mr. Jaharis had had a discussion with
22 Schering-Plough at a senior level, that we should open
23 up some discussions and send them information on our
24 product.

25 Q. Who is Mr. Jaharis?

1 A. Mr. Jaharis is the chairman of the company.

2 Q. There's an arrow halfway down that page, and
3 underneath the arrow reads, "MJ - send label."

4 What does that refer to?

5 A. This refers to Mr. Jaharis suggesting that we
6 send them the labeling section of our NDA, which
7 concisely and probably accurately explains where
8 Niaspan is in its approval process at the FDA, and
9 that's what was happening at the time.

10 Q. Underneath that reads, "DMB - not enough."

11 A. Under that it remarks -- it's a remark by Dan
12 where he said, well, we ought to send them more than
13 just the labeling section, and Dan and I then discussed
14 what else we would likely include in an initial package
15 to Schering-Plough.

16 Q. And underneath that, can you make out the last
17 half of that line, "Pages of S-1"? What does that
18 refer to?

19 A. S-1 are pages from the registration statement.

20 Q. Is this information in the notes the type of
21 information which you'd give a company interested in
22 reviewing your product?

23 A. Yes.

24 Q. The next point is, "CDA review/update."

25 What does that refer to?

1 A. That refers to Dan discussing with me that we
2 would need to have a confidential disclosure agreement
3 which needed to be updated, because we had one that was
4 still active from some years ago, but we wanted to have
5 one that was revised and redated to account for the
6 current discussions that we were about to open up.

7 Q. Let's turn to CX 532 marked in your binder.
8 Mr. Patel, do you recognize this document?

9 A. I do.

10 Q. And what is it?

11 A. It's another note from me to Dan following a
12 discussion with Karin Gast.

13 Q. So, you prepared this?

14 A. I did.

15 Q. It's dated January 22nd, 1997. Was it prepared
16 at or about that time?

17 A. It was.

18 Q. And did you prepare CX 532 in the ordinary
19 course of business?

20 A. I did.

21 MS. APORI: At this time, Your Honor, I offer
22 CX 532 into evidence.

23 JUDGE CHAPPELL: Any objection?

24 MR. NIELDS: No objection, Your Honor.

25 MR. CURRAN: Again, Your Honor, I'm pleased to

1 say no objection.

2 JUDGE CHAPPELL: CX 532 is admitted.

3 (Commission Exhibit Number 532 was admitted
4 into evidence.)

5 BY MS. APORI:

6 Q. Mr. Patel, what was discussed during this phone
7 call?

8 A. This was my discussion with Karin explaining
9 that we had quite a lot more information compared to
10 the earlier discussions some years before and that we
11 had filed an NDA which was in review at the moment and
12 that I would send her a new confidential disclosure
13 agreement to execute.

14 Q. Okay. Mr. Patel, I ask you to please turn to
15 CX 536 in your binder. Do you recognize this document?

16 A. I do.

17 Q. And what is it?

18 A. It's a cover note with our standard
19 confidential disclosure agreement which we signed and
20 sent to them for review.

21 Q. Did you prepare the cover letter?

22 A. I did.

23 Q. I'd ask you to turn to the final page of the
24 exhibit. There's a signature written above the line.
25 Do you recognize that signature?

1 A. I do.

2 Q. And whose is it?

3 A. It's Dan Bell's signature.

4 Q. The cover letter to CX -- the cover letter to
5 this exhibit is dated January 30th, 1997. Was it
6 prepared at or about that time?

7 A. It was.

8 Q. And did you prepare CX 536 in the ordinary
9 course of business?

10 A. I did.

11 MS. APORI: At this time, Your Honor, I offer
12 CX 536 into evidence.

13 MR. NIELDS: No objection.

14 MR. CURRAN: No objection, Your Honor.

15 JUDGE CHAPPELL: CX 536 is admitted.

16 (Commission Exhibit Number 536 was admitted
17 into evidence.)

18 BY MS. APORI:

19 Q. Mr. Patel, please turn to the next page in your
20 binder, that's CX 519. Do you recognize this document?

21 A. I do.

22 Q. And what is it?

23 A. It's a note from Karin to me with the executed
24 secrecy -- confidential disclosure agreement.

25 Q. Was it signed by both parties?

1 A. It was.

2 Q. Okay. I'd ask you to turn to the final page of
3 CX 519. Do you recognize this page?

4 A. I do.

5 Q. And what is it?

6 A. This is my note to Karin subsequent to the
7 execution of the confidential disclosure agreement
8 outlining the package that I had attached that
9 describes various aspects of Niaspan.

10 Q. It's dated February 10th, 1997. Do you recall
11 preparing it at or about that time?

12 A. I do.

13 Q. And did you prepare this in the ordinary course
14 of business?

15 A. I did.

16 MS. APORI: At this time, Your Honor, I offer
17 CX 536 into evidence.

18 JUDGE CHAPPELL: Any objection?

19 MR. NIELDS: No objection.

20 MR. CURRAN: No objection, Your Honor.

21 JUDGE CHAPPELL: What's that exhibit number,
22 Counselor? I thought we already had 536.

23 MS. APORI: I apologize, that's CX 519, I
24 apologize.

25 JUDGE CHAPPELL: Are we sure it's 519?

1 MS. APORI: I'd like to offer CX 519 into
2 evidence.

3 JUDGE CHAPPELL: Any objection to CX 519?

4 MR. NIELDS: No, Your Honor.

5 MR. CURRAN: I don't have an objection, Your
6 Honor, but I'm a little confused. I'm not sure what it
7 is I'm looking at if it's on the screen here. Is that
8 536?

9 MR. NIELDS: It's the last page of 519.

10 MR. CURRAN: Okay, with the understanding that
11 what's on the screen is not CX 536, I have no objection
12 to the admission of 536, Your Honor. Or 519.

13 JUDGE CHAPPELL: That's good, because 536 has
14 already been admitted, Mr. Curran.

15 MR. CURRAN: I wanted to be perfectly clear.

16 JUDGE CHAPPELL: Okay, I'm not sure if we are
17 now. What about 519?

18 MR. CURRAN: No objection to that, Your Honor.

19 JUDGE CHAPPELL: Okay, CX 519 is admitted.

20 (Commission Exhibit Number 519 was admitted
21 into evidence.)

22 BY MS. APORI:

23 Q. Mr. Patel, after the confidentiality agreement
24 was signed by Schering and Kos, did you send Ms. Gast
25 the information that you discussed in your previous

1 conversation with her?

2 A. I did.

3 Q. I again ask you to turn to the final page of
4 CX 519, AAA 0000051. What was included in the packet
5 of information that you sent to Schering?

6 A. What was included was as listed here in four
7 sections. Aspects relating to the profile of Niaspan
8 taken from the IPO registration statement. A copy of
9 the labeling section of Niaspan from the NDA that was
10 under review at the FDA. A page that we had prepared
11 at Kos that summarized the main label that was being
12 proposed for Niaspan. And lastly, a publication in a
13 medical journal on Niaspan.

14 Q. As to the first item, Niaspan profile taken
15 from the IPO statement, was that public information?

16 A. That was.

17 Q. And the second item, copy of proposed labeling
18 for Niaspan, including the indications portion, was
19 that publicly available information?

20 A. No.

21 Q. The third page prepared by Kos, the preliminary
22 labeling indications, was that publicly available?

23 A. No.

24 Q. Did the packet of information, the packet
25 containing all four documents, did it contain

1 information on Niaspan and liver toxicity?

2 A. It did.

3 Q. And what was included, what type of information
4 was included about liver toxicity and Niaspan?

5 A. It included our experience with Niaspan, our
6 measurements of liver enzymes during the studies that
7 we had conducted.

8 Q. Did the packet of information include
9 information on Niaspan and flushing?

10 A. It did.

11 Q. And what was included regarding flushing?

12 A. Again, our clinical experience from our trials
13 of Niaspan and flushing, observations of flushing in
14 patients that we had studied.

15 Q. Did the packet of information contain
16 information on the safety profile of the drug?

17 A. It did.

18 Q. And what type of information was within the
19 safety profile for Niaspan?

20 A. Principally in connection with the liver
21 effects that I've just mentioned, the flushing effects
22 that I've just mentioned, and for that matter any other
23 adverse events that we had noted during our clinical
24 studies.

25 Q. And did it contain information on the efficacy

1 of Niaspan, the packet that you sent to Schering?

2 A. It did.

3 Q. And what type of information was included on
4 the efficacy of Niaspan?

5 A. Again, from patient experience in the studies
6 that were in the NDA, it included considerable
7 information regarding the effects of Niaspan on various
8 lipoprotein fractions.

9 Q. And you sent this packet of information to Ms.
10 Gast in early February. Did anyone from Schering after
11 that point request additional information?

12 A. More information had -- was provided in
13 subsequent interactions. This was just a summary of
14 the initial package that we sent.

15 Q. The letter ends with the statement, "We look
16 forward to hearing from you with an indication of the
17 level of Schering's interest."

18 Did you hear from Schering?

19 A. We did.

20 Q. Did the representatives of Schering and Kos
21 have a face-to-face meeting?

22 A. That was the next interaction.

23 Q. And were you at that meeting?

24 A. I was.

25 Q. I ask you to turn to page 76 -- excuse me, to

1 what's been marked as CX 769 in your binder. Mr.
2 Patel, do you recognize this document?

3 A. I do.

4 Q. In your binder, we took the liberty of blowing
5 up the pages -- the page of your notes into two
6 separate pages.

7 And what is this document?

8 A. These are my handwritten notes of that meeting
9 by -- with Schering and Kos in Miami.

10 Q. It's dated April 9th, 1997. Do you recall, was
11 it prepared at or about that time?

12 A. It was.

13 Q. And was it prepared in the ordinary course of
14 business?

15 A. It was.

16 MS. APORI: At this time, Your Honor, I offer
17 CX 769 into evidence.

18 MR. CURRAN: No objection from Upsher-Smith,
19 Your Honor.

20 MR. NIELDS: May I have just a moment, Your
21 Honor?

22 JUDGE CHAPPELL: Yes.

23 MR. NIELDS: Your Honor, I've been wrong before
24 about matters of this type, but I think this may be an
25 in camera document, and I would simply inquire --

1 JUDGE CHAPPELL: First of all, let's
2 immediately take it off the screen, please.

3 Now, let's decide while we pause. Someone let
4 me know, verify whether or not it's in camera.

5 MS. APORI: Your Honor, we will have areas of
6 Mr. Patel's testimony that will be in camera documents.
7 I intend to offer the Court ample notice to clear the
8 courtroom before we raise those documents, but 769 was
9 not granted in camera treatment.

10 MR. NIELDS: It is on our list of in camera,
11 Your Honor. We're not immune from error in this
12 regard, but it is apparently on our list of documents
13 that have been granted in camera status.

14 MR. CAMPBELL: Your Honor, may I be heard?
15 John Campbell on behalf of Kos.

16 Your Honor, we would like -- we had asked this
17 document to be considered in camera. I don't think it
18 was on the list of the documents that you did approve,
19 but I think that the rationale for our in camera motion
20 applies to this document, clearly relates to his -- Mr.
21 Patel's negotiations with other companies and may, in
22 fact, include competitive information that ought to be
23 held in camera.

24 JUDGE CHAPPELL: So, do I understand you to say
25 that you did not request in camera treatment --

1 MR. CAMPBELL: Yes, we did, Your Honor. You
2 had denied it initially, and then -- you denied our
3 motion as inadequate initially, and then you delineated
4 a number of documents. My understanding is this is not
5 one of them that you granted in camera inspection -- in
6 camera treatment of, but --

7 JUDGE CHAPPELL: Well, I'm not -- I'm not
8 interested in your understanding, sir. I need to know.
9 Is this a document I considered and rejected for in
10 camera or not?

11 MR. CAMPBELL: I don't know what your rationale
12 was, because the first ruling you had was we had
13 provided inadequate reasons to treat the documents as
14 in camera --

15 JUDGE CHAPPELL: Probably because there was no
16 affidavit or something lacking.

17 MR. CAMPBELL: Right, exactly.

18 JUDGE CHAPPELL: That happens all the time, but
19 then when it was refiled, was this an exhibit on
20 that -- a part of that motion for in camera treatment?

21 MR. CAMPBELL: Yes, Your Honor. Yes, it was.

22 JUDGE CHAPPELL: So, then, was this document
23 granted in camera status?

24 MR. CAMPBELL: No, Your Honor, it was not.

25 JUDGE CHAPPELL: So, I rejected this one?

1 MR. CAMPBELL: Yes, Your Honor.

2 JUDGE CHAPPELL: Mr. Curran, have you
3 determined otherwise?

4 MR. CURRAN: Your Honor, we have --

5 JUDGE CHAPPELL: We have three lists here, at
6 least.

7 MR. CURRAN: We have only a sporting interest
8 in this particular document. If you can give us just a
9 minute, our spreadsheet indicates that in camera
10 treatment was granted for this. We are now trying to
11 locate Your Honor's order to that effect.

12 MR. CAMPBELL: Well, I don't have the order
13 right here, Judge, but my understanding, this was not,
14 but what I would ask that the Court do at this point --

15 JUDGE CHAPPELL: Well, if I already denied it,
16 I don't have any new evidence. I am not going to
17 reconsider that, sir.

18 MR. CAMPBELL: Okay, can you give us a moment
19 to get the order then, Judge?

20 JUDGE CHAPPELL: Yes.

21 MR. CAMPBELL: Thank you.

22 (Pause in the proceedings.)

23 MR. CURRAN: Your Honor, can I give you an
24 update on the status of our review?

25 JUDGE CHAPPELL: Of your list regarding this

1 document?

2 MR. CURRAN: Yes. According to our record
3 keeping, Your Honor granted in camera status to this
4 document on February 12th, 2001. We believe we know
5 why there may be some confusion, and that is because in
6 camera treatment was granted identifying the document
7 by Bates range rather than by exhibit number, and that
8 could have created some uncertainty in the minds of
9 certain observers.

10 JUDGE CHAPPELL: And I didn't recall excluding
11 any of the Kos documents after they got the proper
12 motion on file. I thought they were all granted in
13 camera. You said February 20th 2001. You meant 2002,
14 right?

15 MR. CURRAN: I did, Your Honor, yes, thank you.

16 MR. CAMPBELL: And Your Honor, when I went
17 through your ruling, it appeared that you had excluded
18 the public documents of the registration statement,
19 which, you know, made sense to us, and I thought at
20 least on -- but the documents relating to the
21 negotiations I thought you had included, but I was not
22 under the impression that this one was.

23 JUDGE CHAPPELL: So, we have two lists saying
24 it is in camera, one list saying it is not? Has anyone
25 found the order yet? There wouldn't have been -- I

1 don't think they would have been listed by exhibit
2 number at that time.

3 MR. CAMPBELL: Here it is. We've got the
4 order.

5 Your Honor, it is not included on the order
6 according to the Bates numbers, and I'm not --

7 JUDGE CHAPPELL: Is this one like others I've
8 seen where there's more than one copy with more than
9 one Bates number?

10 MS. APORI: I don't believe so, Your Honor.

11 JUDGE CHAPPELL: Okay, then we won't go into in
12 camera session at this time.

13 MR. CURRAN: Thank you, Your Honor.

14 JUDGE CHAPPELL: Mr. Nields, thank you for
15 raising that. When in doubt, we always want to verify
16 before we expose an in camera document. Thank you.

17 MR. NIELDS: Your Honor, I think I was asked
18 whether I objected or not to this document, and I
19 believe I do not object to it. The only problem is I
20 have never been able to read all of it, and there is a
21 lingering possibility there's some hidden hearsay. I
22 don't believe there is, but I would be willing to not
23 object subject to the possibility that something may
24 arise during the testimony about it that will inform me
25 that it has something in it that I don't yet know.

1 JUDGE CHAPPELL: So, since she's laid the
2 foundation that it's a business record, you are not
3 objecting at this time until you hear more of the
4 direct exam?

5 MR. NIELDS: Correct.

6 JUDGE CHAPPELL: Okay, thank you. With that
7 qualification, CX -- what number is it?

8 MS. APORI: 769.

9 JUDGE CHAPPELL: -- CX 769 is admitted.

10 Mr. Curran, you had not objected, correct?

11 MR. CURRAN: Correct, Your Honor, no objection.

12 JUDGE CHAPPELL: Thanks.

13 (Commission Exhibit Number 769 was admitted
14 into evidence.)

15 BY MS. APORI:

16 Q. Mr. Patel, during the meeting on April 9th,
17 1997, who participated on behalf of Kos?

18 A. Dan Bell, David Heatherman, John Kalimtsis and
19 myself.

20 Q. I see a few names written underneath, some
21 initials, Ray Russo, Karin Gast, Dave Grewcock, Antonia
22 DeMola. Did these people participate on behalf of
23 Schering?

24 A. That's right.

25 Q. Underneath the names are two horizontal lines.

1 Can you tell us what that refers to?

2 A. This refers to an initial comment made by David
3 Heatherman where he set out his basis for a cooperation
4 or his needs.

5 Q. And what did he identify as those needs?

6 A. His needs refer to having a cooperation
7 involving a product in exchange. That's what's
8 referred to as "QPQ," which is quid pro quo. The first
9 item refers to primary calls, which is David Heatherman
10 explaining he wanted the cooperation to provide
11 promotional detailing in a primary position to
12 physicians. The middle bullet I can't make out from
13 this handwriting.

14 Q. Okay. Mr. Patel, directing your attention to
15 the right-hand side of the page, or in the blown-up
16 portion of your notes the second page, there's a short
17 listing at the top that reads, "Stock, up front, big
18 partner."

19 What do these terms refer to?

20 A. These terms -- these are three points that
21 summarize my own views about what would be needed by us
22 in a cooperation with Schering-Plough.

23 Q. Why would stock or an equity investment be an
24 important part of the deal?

25 A. It's an important sign for Kos, because it's a

1 sign of commitment from the large pharmaceutical
2 company that wants to cooperate with us.

3 Q. And was up-front payment also an important part
4 of the licensing deal with Schering?

5 A. Yes, it was.

6 Q. And why was that important?

7 A. It's also a sign of commitment right at the
8 commencement of any cooperation.

9 Q. And did you communicate this to Schering
10 representatives during the meeting?

11 A. I believe I did.

12 Q. Internally, in your discussions with other Kos
13 executives, did you discuss the idea of an up-front
14 payment as related to a deal with Schering for Niaspan?

15 A. I'm sorry, could you repeat the question?

16 Q. Sure. Internally, in your discussions with
17 other Kos executives, did you discuss the idea of an
18 up-front payment for Niaspan in your dealings with
19 Schering?

20 A. May I ask if your question is prior to this
21 meeting or during the whole process of our discussions
22 with Schering-Plough?

23 Q. Prior to this meeting.

24 A. I'm not sure if we necessarily discussed the
25 specifics prior to the meeting.

1 Q. Did you have occasion to discuss it after the
2 meeting?

3 A. I believe we would have discussed these main
4 elements subsequent to this meeting in the
5 conversations and in the negotiation process.

6 Q. How much did Kos expect or hope for in terms of
7 an up-front payment?

8 A. We never arrived at a hard dollar figure for
9 up-front payments. It was important for us to make
10 sure that concept was conveyed so that they would in
11 principle accept the concept of an up-front payment.

12 Q. Further down the page, looking back again at
13 CX 769, there's a heading reading "Open Issues," and
14 what does that refer to?

15 A. This relates to a number of items that we would
16 have to discuss in more detail in subsequent meetings
17 as part of the negotiation process and as part of the
18 understanding process of Niaspan and its merits.

19 Q. Looking underneath that it says, "Final
20 labeling," and what would that -- what issue would that
21 refer to?

22 A. Well, the information we sent to them when we
23 started these discussions involved draft labeling that
24 was currently being reviewed at the FDA, and this point
25 refers to Schering's obvious need to want to know what

1 the final labeling would be when the product is
2 actually approved in the coming months.

3 Q. The next item, "Launch Timing," what does that
4 refer to?

5 A. This refers to the fact that we had a view as
6 to when we think we would get approval, and that
7 factors into when we actually end up launching, because
8 if there's a slight delay in the approval, there would
9 be a slight delay in the launch. We basically
10 recognized that there would be a launch at the end of
11 '97 or in the early part of 1998.

12 Q. The third item underneath reads, "Distrib" and
13 I believe "Manu issues."

14 Can you explain what that refers to?

15 A. This refers to Schering at some point in the
16 discussion wanting to know all of the various
17 distribution and manufacturing plans that we had in
18 place.

19 Q. Underneath that it says "Patents," and what
20 does that refer to?

21 A. This refers to a topic that we started
22 discussing at this meeting, and we fully expected to
23 discuss in future cooperation discussions relating to
24 the patents and the patent estate behind Niaspan.

25 Q. And the following point, "Global," there's an

1 arrow, "Pricing, pricing, pricing."

2 What does that refer to?

3 A. This refers to a discussion about whether this
4 product would be available in a global arrangement
5 covering global -- rights to global territories. It
6 refers to the conclusion made at the meeting that we
7 would concentrate on the U.S., because a number of
8 unknowns had to be resolved with respect to Niaspan's
9 potential abroad and in particular with respect to the
10 kind of pricing that we would achieve subject to
11 government approvals.

12 Q. Did Kos have concerns about achieving a
13 specific level of pricing for Niaspan in Europe?

14 A. I think both parties recognized that pricing
15 was still something that we needed to look into when it
16 came to discussing the potential of this product in
17 many territories outside the U.S.

18 Q. Do you recall anyone from Schering expressing
19 any concerns about the clinical profile of Niaspan
20 during that meeting?

21 A. I don't believe so.

22 Q. And can you tell me if at that meeting Schering
23 requested additional information as to the clinical
24 profile of Niaspan?

25 A. I believe Schering-Plough did ask for that

1 information in subsequent -- as a normal course of
2 subsequent discussions.

3 Q. Just to be clear, was that during the April 9th
4 meeting or in subsequent discussions?

5 A. At this meeting, there were a number of things
6 that we needed to cover. They are primarily summarized
7 under Next Steps in this note, and I'm quite sure
8 matters relating to efficacy as well as other topics
9 were highlighted under the next steps and as part of
10 their review process of the product.

11 MS. APORI: Your Honor, now we are about to
12 begin a line of questioning dealing with documents that
13 have been granted in camera status.

14 JUDGE CHAPPELL: Okay, Mr. Campbell, step
15 forward, please, sir.

16 MR. CAMPBELL: Yes, sir.

17 JUDGE CHAPPELL: After the last exchange we all
18 had about that document, I'm still not certain whether
19 it was considered and rejected by me. Are you sure --
20 do you know?

21 MR. CAMPBELL: Well, it was -- I'm sorry.

22 JUDGE CHAPPELL: Do you know if it is one that
23 was rejected by me or is it one that in camera
24 treatment was never requested?

25 MR. CAMPBELL: It was requested, Your Honor,

1 but it was not on that list, and I was not -- when I
2 read the list, I wasn't sure why, but we're content
3 with it now if that's an issue. I don't have any
4 objection to it.

5 JUDGE CHAPPELL: Okay, thank you.

6 So, at this time, Ms. Apori, we will go into in
7 camera session. I will have to ask the public to leave
8 the courtroom.

9 (The in camera testimony continued in Volume
10 31, Part 2, Pages 7600 through 7658, then resumed as
11 follows.)

12 JUDGE CHAPPELL: Ms. Apori, let's wait until
13 the public has a chance to come back in.

14 Go ahead.

15 BY MS. APORI:

16 Q. Can you please turn to CX 508 in your binder.
17 Do you recognize this document?

18 A. I do.

19 Q. And can you identify it for us?

20 A. This is my own notes regarding a status of a
21 discussion with one of the individuals at SmithKline.

22 Q. It's dated August 13th, 1997. Was it prepared
23 at or about that time?

24 A. It was.

25 Q. And was it prepared in the ordinary course of

1 business?

2 A. It was.

3 MS. APORI: At this time, Your Honor, I'd like
4 to offer CX 508 into evidence.

5 MR. CURRAN: No objection from Upsher-Smith.

6 MR. NIELDS: No objection, Your Honor.

7 JUDGE CHAPPELL: CX 508 is admitted.

8 (Commission Exhibit Number 508 was admitted
9 into evidence.)

10 BY MS. APORI:

11 Q. Mr. Patel, what product does this document
12 refer to?

13 A. Niaspan and the combination product containing
14 Niaspan.

15 Q. In your discussions with SmithKline Beecham,
16 did you reach a point where you discussed proposed
17 terms of a licensing agreement?

18 A. This is a note to the conversation that I had
19 with the individual, a senior individual at SmithKline.
20 She wanted to go forward with discussions about how we
21 would do an arrangement, and I'm conveying to her the
22 main elements of an arrangement that she would have to
23 consider if she were, in fact, going to make a
24 proposal.

25 Q. I direct your attention towards the bottom of

1 the page, if you can look at item number 4 under the
2 Notes section, it reads, "Non-U.S. rights would be
3 available also based upon an appropriate up-front fee
4 and typical license terms."

5 What does that refer to?

6 A. That refers to me stating that they would be --
7 if they're interested in our product, Niaspan and the
8 combination, beyond the U.S., then this would be the
9 basis on which we would do an arrangement; namely, a
10 typical license that would involve some up-front fee
11 consideration.

12 Q. And what does the up-front -- how much was Kos
13 expecting in terms of an up-front fee?

14 A. I didn't actually propose a number here. I
15 suspect I had an idea in my mind if we were to get to
16 that kind of a proposal with numbers.

17 Q. Can you tell me what "typical license terms"
18 refers to?

19 A. It would have been an up-front fee in the order
20 of \$10 million.

21 Q. Also looking at point 6 under your notes, did
22 Kos request an equity investment from SmithKline
23 Beecham?

24 A. Yes, as a possible addition or replacement for
25 up-front fee discussions and milestone fee discussions.

1 Q. Did you propose an amount for how much this
2 equity investment would be?

3 A. No, I didn't.

4 Q. I ask you to turn to the previously admitted
5 document CX 507 in your binder. Mr. Patel, looking at
6 the second full paragraph on that line, "We look
7 forward to receiving the patent materials so that we
8 can complete our analysis," did SmithKline Beecham
9 request patent information on Niaspan?

10 A. They did.

11 Q. Did the negotiations between Kos and SmithKline
12 Beecham result in a license agreement?

13 A. No, it did not.

14 Q. Now, Mr. Patel, you've spoken to numerous
15 companies about licensing opportunities for Niaspan
16 outside of the United States. During the time that you
17 were with Kos, did you ever find a partner?

18 A. No.

19 Q. In your search for a European partner,
20 including the companies that we've just discussed, did
21 anyone make an offer of \$60 million in noncontingent
22 payment for Niaspan alone outside of the United States?

23 A. No.

24 MS. APORI: Thank you. No more questions at
25 this time.

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1 JUDGE CHAPPELL: Any cross?

2 MR. NIELDS: I think so, Your Honor. May I
3 have just a moment? I actually have some binders, too,
4 which I think would be efficient to give the witness
5 and complaint counsel and the Court and the court
6 reporter.

7 JUDGE CHAPPELL: Go ahead.

8 (Pause in the proceedings.)

9 MR. NIELDS: I'm ready when the Court is.

10 JUDGE CHAPPELL: You may proceed.

11 CROSS EXAMINATION

12 BY MR. NIELDS:

13 Q. Good afternoon, Mr. Patel.

14 A. Good afternoon.

15 Q. I take it that in the first half of 1997, Kos
16 was looking for a marketing partner for Niaspan, is
17 that correct, in the U.S.?

18 A. That is correct.

19 Q. And you were looking for a kind of a co-promote
20 arrangement. Is that correct?

21 A. That was the best arrangement we were looking
22 for.

23 Q. Okay. You weren't looking for an outright
24 license to some other company.

25 A. That's correct.

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1 Q. And I take it the concept was that Kos had a
2 very promising product, which was Niaspan, and you were
3 looking for a partner that could give you some sales
4 and marketing muscle.

5 A. Yes, in order to maximize the potential of the
6 product.

7 Q. And the concept was that you'd put in the
8 product, they would put in the marketing muscle, and
9 there would be some sort of sharing or splitting of the
10 profits.

11 A. Yes. If I may clarify, it was a -- it was
12 based on us putting the product so that they could
13 market it as well as ourselves. We had an intent to
14 have a small marketing infrastructure as well; hence,
15 co-promotion.

16 Q. And I take it you were looking for a big
17 company.

18 A. Yes.

19 Q. So that they would be able to give you major
20 sales, detailing and marketing support.

21 A. That's correct.

22 Q. And I take it you talked to more than one
23 company in your search for a marketing partner for the
24 U.S.?

25 A. That's right.

1 Q. But one of them was Schering?

2 A. That's right.

3 Q. And I take it there came a time when Schering
4 actually gave you a written proposal.

5 A. That's correct.

6 Q. Now, focusing on the prelaunch period before
7 you actually launched, did any other company give you a
8 written proposal besides Schering?

9 A. I don't believe so.

10 Q. Now, your first contact was with Karin Gast?

11 A. That's right.

12 Q. And she contacted Kos this time. Is that
13 right?

14 A. That's right, based on an initial discussion
15 between our chairman and a senior representative at
16 Schering.

17 Q. And the person she contacted was you.

18 A. That's right.

19 Q. And this was in January of 1997?

20 A. Yes. Yes.

21 Q. And then you had a couple of conversations with
22 her on the -- by telephone?

23 A. That's right.

24 Q. And then there was a confidentiality agreement
25 that was sent and signed by both parties?

1 A. That's right.

2 Q. And then you, pursuant to the confidentiality
3 agreement, sent Karin Gast and Schering some materials
4 relating to Niaspan.

5 A. That's right.

6 Q. And those, as I recall, are I think kind of a
7 product profile on Niaspan that came out of your IPO,
8 proposed labeling, a one-page document showing various
9 indications that you were hoping to get from FDA, and a
10 reprint of an article about some clinical trials on
11 Niaspan.

12 A. That's correct.

13 Q. And I take it -- that was in February of '97?

14 A. That's right.

15 Q. And then Schering had a period of time within
16 which they were able to review the material?

17 A. That's right.

18 Q. And I take it things were a little bit busy at
19 Kos right around that time, with the IPO?

20 A. That's correct, yes.

21 Q. The IPO happened in March?

22 A. March '97.

23 Q. And pursuant to that IPO, Kos raised a little
24 more than \$60 million by selling stock to the public?

25 A. That's correct.

1 Q. And that stock represented, if you know, about
2 a little under 30 percent interest in the company?

3 A. That's correct.

4 Q. And the rest of it was owned by Mr. Jaharis?

5 A. Mr. Jaharis was the principal owner of the
6 remaining portion, yes.

7 Q. And then after Schering then had a chance to
8 review the materials, there was a meeting in Miami in
9 April.

10 A. That's right.

11 Q. Is that correct?

12 And I think you've identified some notes that
13 you took of that meeting that are dated April 9th.

14 A. That's right.

15 Q. And I take it several Schering people actually
16 traveled to Kos headquarters in Miami for that meeting.

17 A. Correct.

18 Q. And that was Mr. Russo, Karin Gast, a David
19 Grewcock and Antonia DeMola?

20 A. That's right.

21 Q. And I take it you had a meeting there with them
22 at which you exchanged views and ideas and concepts
23 about the possible co-promotion of Niaspan?

24 A. That's correct.

25 Q. Now, you've already testified about this set of

1 notes, and our version of it may look a little
2 different, but it's I think a xerox of the same -- the
3 same document, and you'll find it in binder 1 at --
4 bear with me one moment -- CX 769.

5 A. Is it towards the back?

6 Q. It is. It's about, oh, 85 percent of the way
7 through in terms of volume.

8 A. Got it.

9 Q. Okay?

10 A. Okay.

11 Q. And in that -- in those notes, you recorded
12 various things that happened at the meeting.

13 A. That's right.

14 Q. Now, I take it one of the things that happened
15 is that the Schering people told you that they had a
16 current emphasis at Schering on cardiovascular
17 products.

18 A. They've always had an interest and a presence
19 in cardiovascular products.

20 Q. But they said that at the meeting, didn't they?

21 A. That's right.

22 Q. And did they mention in particular a product
23 they had in development that was in phase II trials and
24 that was a new chemical entity?

25 A. That's correct, it was in the area of

1 cholesterol, which is the very reason they wanted to
2 talk to us about this type of an arrangement.

3 Q. On Niaspan?

4 A. On Niaspan.

5 Q. Because Niaspan was also for cholesterol.

6 A. That's right.

7 Q. And did they explain that they were hoping to
8 get a presence in the cholesterol marketplace in
9 anticipation of the eventual launch of their phase II
10 new chemical entity?

11 A. That's correct.

12 Q. Did they also mention a product called
13 Integrelin in the cardiovascular area that they were --
14 had recently worked on?

15 A. Yes, that was a product that they were
16 co-promoting with another company.

17 Q. And did they tell you that they had done some
18 market research on Niaspan?

19 A. Yes.

20 Q. And did they tell you that they had, in fact,
21 contacted their advisory board about Niaspan?

22 A. Yes, I remember that conversation.

23 Q. And their advisory board means -- refers, I
24 take it, to cardiologists, experts in the field that
25 they had contacted to get their views about Niaspan?

1 A. That's right.

2 Q. And did they spend some time at that meeting
3 describing their capabilities as a marketing partner
4 for Kos?

5 A. They did.

6 Q. And did they outline their key strengths that
7 would lend themselves towards a cooperation with you on
8 Niaspan?

9 A. Yes, they summarized their presence in the
10 cardiovascular market.

11 Q. Did they talk for a while about their expertise
12 in managed care?

13 A. Managed care, total number of reps, the
14 experience of some of the individuals that were at the
15 meeting, and from -- either from Schering-Plough or
16 before they joined Schering-Plough.

17 Q. In other words, some of the people from
18 Schering who were there made reference to their
19 experience at other companies?

20 MS. APORI: Objection, Your Honor, hearsay.

21 MR. NIELDS: I'm not offering this for the
22 truth of the matter asserted, Your Honor. I'm offering
23 it in order to demonstrate Schering's focus, interest
24 on this product.

25 MS. APORI: Your Honor, then I'd like some

1 clarification as to whether the line of questions
2 leading up to this refers to -- goes to the truth.

3 JUDGE CHAPPELL: Well, he said that one doesn't
4 go to the truth, so the objection's overruled on that
5 question.

6 BY MR. NIELDS:

7 Q. And did they talk about --

8 JUDGE CHAPPELL: I don't think you got an
9 answer.

10 MR. NIELDS: Oh, maybe I didn't.

11 JUDGE CHAPPELL: I overruled the objection.

12 MR. NIELDS: I'm sorry, Your Honor.

13 (The record was read as follows:)

14 "QUESTION: In other words, some of the people
15 from Schering who were there made reference to their
16 experience at other companies?"

17 THE WITNESS: That's correct.

18 BY MR. NIELDS:

19 Q. And did the Schering folks talk about their
20 experience in direct-to-patient advertising?

21 A. There was a discussion on that subject, yes.

22 Q. And did they make a reference to their ability
23 to help Kos in phase IV clinical trials?

24 A. Yes, they did.

25 Q. Now, do you recall, Mr. Patel, that they

1 brought down some sort of slides or overheads or
2 demonstratives, so to speak, that they referred to when
3 they were addressing this?

4 A. I believe they did.

5 Q. Now, if you turn back to an Exhibit Number SPX
6 112, which I think is three exhibits backwards in your
7 book, it begins with a Schering memorandum of the same
8 meeting that's in typewritten form. I'm not going to
9 ask you questions about that, but right behind that
10 you'll find -- I don't know, it's about 15 pages maybe
11 of what look to be slides or overheads or
12 demonstratives. Do you see those?

13 A. Yes.

14 Q. If you look at the second one of those -- and
15 it has a Bates stamp SP 002751. Do you see that one?

16 A. Yes.

17 Q. It's headed Opportunities for Success, and the
18 first bullet is, "Fast, powerful launch, muscle
19 momentum, significant physician education effort
20 required from day one."

21 A. Yes.

22 Q. Do you recall Schering addressing their view
23 that a successful launch of Niaspan would require
24 muscle at the outset and significant physician
25 education effort?

1 A. Yes, that's what we would expect in the
2 partnership.

3 Q. And then at the bottom there's a bullet,
4 "Direct-to-patient promotion"?

5 A. Correct.

6 Q. I think I've already asked you if they
7 discussed that subject with you, and you indicated that
8 they had. Is that correct?

9 A. That's right.

10 Q. Then if you turn the page to the page Bates
11 stamped 002752, it says, "Key Schering Capabilities."

12 I assume that refers to capital K, Key
13 Schering, although it's not clear, and the first bullet
14 says, "Strategic fit with CV franchise, long-term
15 commitment to lipid reduction," and do you recall
16 Schering discussing their commitment to and experience
17 in cardiovascular?

18 A. I do.

19 Q. And then there's another bullet, it says, "Key
20 field force demonstrated CV success," and then it
21 refers to three products, Imdur, Nitro-Dur and K-Dur.

22 Do you recall them talking about their
23 experience in cardiovascular, referring to those three
24 products?

25 A. I do.

1 Q. And of course, those were originally Key
2 Pharmaceuticals products, and Key Pharmaceuticals had
3 originally been owned by Mr. Jaharis.

4 A. That's correct.

5 Q. And some of the people at Kos had been
6 previously at Key.

7 A. That's correct.

8 Q. And then it refers to managed care ITG efforts,
9 and I think you've already said that you recalled
10 Schering talking about its experience and expertise in
11 managed care.

12 A. That's right.

13 Q. Correct?

14 And then if you turn the page to the next
15 document, which bears Bates stamp number 2753, it
16 continues, "Key Schering Capabilities," and it refers
17 to distribution, direct-to-patient efforts, vast
18 experience, possible cost synergies, clinical trial and
19 phase IV efforts, and again, do you recall Schering
20 talking about its experience and ability to help Kos in
21 those areas?

22 A. I do.

23 Q. And then if you go to -- I think it's three
24 pages later, it's SP 002755 -- maybe it's two pages
25 later -- it's a page headed Marketing Research Efforts.

1 Do you see that?

2 A. I do.

3 Q. And it says, "Two teleconferences with
4 cardiologists and primary care physicians," and it has
5 a number 18, and then it says, "In-depth interviews
6 with key lipid advisory panel," and there's a number
7 12. It says, "Third-party data." It says,
8 "International subsidiaries." It says, "Continuous
9 research in hyperlipidemia market."

10 Do you recall Schering talking to you about the
11 various things they had done in order to gain
12 additional marketing information about a possible
13 launch of Niaspan?

14 A. Correct, yes.

15 Q. In general, Mr. Patel, did Schering endeavor to
16 persuade Kos that Schering would be a good partner?

17 A. Yes, they didn't -- we didn't need to be
18 persuaded. We knew enough about Schering for many,
19 many years, and that's -- you know, it was given that
20 that would -- that Schering would be a good partner,
21 and this confirmed --

22 Q. But notwithstanding that, there was effort made
23 at that meeting by the Schering folks in order to do
24 that, yes?

25 A. Yes.

1 Q. Now, there were some issues, weren't there,
2 that came up at that meeting?

3 A. Yes.

4 Q. Detailing, did that come up?

5 A. Detailing commitment and priority.

6 Q. Um-hum. And do you recall -- I think I forgot
7 to ask you, but you probably said on direct that Mr.
8 Heatherman was there for Kos.

9 A. That's right.

10 Q. Is that correct?

11 A. That's right.

12 Q. And was Mr. Bell there at that meeting?

13 A. Dan Bell was there and John Kalimtsis.

14 Q. Okay. And do you recall Mr. Heatherman
15 indicating that Kos wanted a significant amount of
16 primary details?

17 A. I do.

18 Q. And a primary detail means that when the rep
19 goes into a doctor's office on a particular visit that
20 he will give priority to one product, either he'll
21 mention it first or he'll mention it most.

22 A. Correct.

23 Q. Or she.

24 And do you recall that someone from Schering,
25 was it Mr. Grewcock at some point during the meeting

1 indicated that they, Schering, would be more
2 comfortable with secondary detailings or at least some?

3 MS. APORI: I have the same objection, Your
4 Honor, hearsay.

5 MR. NIELDS: Your Honor, I'm offering this not
6 for the truth. I'm offering it as part of the
7 discussions.

8 JUDGE CHAPPELL: Overruled.

9 THE WITNESS: Heatherman wanted absolute
10 maximum commitment from Schering in the form of first
11 line details. You know, that's sometimes an ideal
12 thing to ask for, but you do ask for it, and then you
13 hear the response, which is, well, we will certainly
14 give it a lot of commitment, but there may be some
15 secondary details that we'll provide as well, because
16 that's the way it works.

17 BY MR. NIELDS:

18 Q. But that was an issue that was a subject of
19 discussion and not entirely resolved at the meeting.
20 Is that right?

21 A. That's right. It certainly wasn't a
22 deal-breaker, because there was going to be some give
23 and take on both sides.

24 Q. And did the issue of something called booking
25 sales come up?

1 A. Yes, it did.

2 Q. And was that described by someone on the
3 Schering side as a "hot button issue"?

4 A. It was.

5 Q. Was that Karin Gast?

6 A. I believe it was.

7 Q. Now, in a co-promotion arrangement, does
8 booking sales refer to the question of which company's
9 books would show that the sales had been made?

10 A. That's correct.

11 Q. So that at the end of the year, for example,
12 when Kos reports on its finances, it will have a line
13 that will say, "Sales," and companies generally like to
14 have that line have a big number at the end of it?

15 A. That's right.

16 Q. And Schering indicated it was important to it
17 to book sales.

18 A. Yes, Schering wanted to book the sales, we
19 wanted to book the sales, we needed to find middle
20 ground if we were going to go forward.

21 Q. And did Schering mention that it didn't want to
22 be in an arrangement where it was simply "rent a sales
23 force"?

24 A. Correct.

25 Q. And was the issue of marketing control, did

1 that come up?

2 A. Yes, it did.

3 Q. And again, would it be fair to say that the Kos
4 people indicated that you wanted to retain essential
5 control over the marketing strategy, and the Schering
6 folks indicated that they wanted to have some input at
7 least into it?

8 A. That's right, the going-in position is we
9 wanted total marketing control, and we recognized,
10 however, that they would want to have some say in the
11 matter, even if it weren't control.

12 Q. And did Karin Gast -- and I take it that issue
13 was not finally resolved during that meeting either.
14 Is that correct?

15 A. That's correct, but it wasn't seen as a
16 deal-breaker at the time.

17 Q. And the booking sales issue was also not
18 resolved at that meeting. Is that correct?

19 A. That's correct.

20 Q. And do you recall Karin Gast asking if at some
21 point in the future Kos would be willing to discuss
22 worldwide sales?

23 MS. APORI: Objection, Your Honor, hearsay.

24 MR. NIELDS: Your Honor, I don't think it could
25 be hearsay, but I'm certainly not offering it for the

1 truth of any matter asserted, just part of the
2 negotiations and discussions.

3 JUDGE CHAPPELL: Overruled.

4 THE WITNESS: Could you repeat the question,
5 please?

6 MR. NIELDS: I think she has to do that.

7 (The record was read as follows:)

8 "QUESTION: And do you recall Karin Gast asking
9 if at some point in the future Kos would be willing to
10 discuss worldwide sales?"

11 THE WITNESS: I do recall that.

12 BY MR. NIELDS:

13 Q. And did Kos say that at some point it would?

14 A. Yes, and I think we generally agreed between us
15 that we would concentrate on the U.S. and cooperation
16 in Europe and the rest of the world would be deferred
17 to a later stage.

18 Q. And then there were some other issues
19 discussed, such as labeling, final labeling, launch
20 timing, distribution and manufacture, patents,
21 cross-license agreement and so forth?

22 A. That's correct.

23 Q. Now, Mr. Patel, at the end of this meeting,
24 what happened? The parties agreed to consider the
25 matter further and get back in touch later?

1 A. That's correct.

2 Q. Now, you indicated in your direct testimony
3 twice, I think, that -- you referred to a note in your
4 handwritten notes, which I am going to have to find
5 again, Exhibit CX 769. Do you have that in front of
6 you?

7 A. Yes, I do.

8 Q. And I think you were referring to a note in the
9 upper right-hand corner where I believe it says -- it
10 has an arrow, and it says, "MPP views are: Stock, up
11 front," and something I can't read.

12 A. "Big partner."

13 Q. "Big partner."

14 And you were asked whether you -- you wrote
15 that, I take it.

16 A. Yes, I did.

17 Q. And I think you were asked whether you
18 mentioned to Schering at that meeting that you wanted
19 the purchase of stock and an up-front payment, and you
20 said -- and I believe I'm quoting you twice -- "I
21 believe so."

22 Do you recall that testimony on direct?

23 A. I do.

24 Q. Now, wouldn't it be more accurate to say that
25 you don't recall whether you told Schering at that

1 meeting that Kos wanted a stock purchase and an
2 up-front payment?

3 A. I know that these were items that were in my
4 mind. I don't recall whether it was I who actually
5 stated them or whether it was something that was
6 discussed that Dan brought up at some point during the
7 end of the conversation.

8 Q. Well, now you've given a third version.
9 Wouldn't it be more accurate to say that you're not
10 sure whether that subject was spoken about at the
11 meeting?

12 A. What I'm saying is that these notes here refer
13 to my views --

14 Q. Understood.

15 A. -- and that I don't recall whether I'm the one
16 who actually said we want stock, up-front and working
17 with a big partner. What I said was I don't recall
18 whether it was Dan who actually brought them up at the
19 meeting. It may well have been Dan. I don't have
20 notes that speak to whether it was he who spoke about
21 these points.

22 I also can't make out whether any of those
23 points were in the final notes under Next Steps, and
24 that's because I don't make out the writing.

25 Q. Now, could you turn to your deposition, which

1 is -- your investigational hearing transcript, which is
2 the very first thing in your binder.

3 A. Okay.

4 Q. Now, would you turn to page -- there's a page
5 that has 43, 44, 45 and 46 on it.

6 A. Forty-three to 46?

7 Q. Yes. Do you have that?

8 A. Yes.

9 Q. And if you look down at the bottom of -- if you
10 look down at the bottom of page 44, can you see that
11 you're being asked about these exact notes with the
12 arrow and the MPP -- by the way, MPP is you, correct?

13 A. That's correct.

14 Q. Mukesh Patel?

15 A. Right.

16 Q. With a middle initial P?

17 A. Right.

18 Q. And the question is:

19 "QUESTION: Can you read what's on the top
20 right-hand side of the page?"

21 And your answer is, "Above the line there's an
22 arrow that says, MPP views are." Then you say, "MPP is
23 myself." Then you say, "These are my views as to what
24 would be crucial to me from a licensing point of view
25 and then arriving at a cooperation with us, and the

1 three things in my mind -- three things in my mind are,
2 stock, which is stock, an investment in the company,
3 Kos, upfront, which upfront payment for rights to our
4 product, and I've written here, big partner, needs to
5 be a named company, a big name company such as
6 Schering-Plough."

7 And then you were asked:

8 "QUESTION: Okay. Excuse me. Were these
9 thoughts you shared at the meeting or are those
10 thoughts that you had?

11 "ANSWER: These are just my thoughts, and I may
12 have explained it to them. I don't recall if I
13 actually went through this."

14 Do you see that?

15 A. I do.

16 Q. And you didn't mention anything about anybody
17 else talking about it there, did you?

18 A. No, because I was being asked about what I
19 thought here.

20 Q. Well, actually, you were asked, "Okay. Excuse
21 me. Were these thoughts you shared at the meeting or
22 are those thoughts that you had?"

23 And you start by answering, "These are just my
24 thoughts," and you conclude by saying, "I don't recall
25 if I actually went through this."

1 Do you recall today if you actually went
2 through that?

3 A. I recall we were discussing those notes at the
4 top of that page. Whether those notes were notes I
5 wrote because we discussed them or because they were
6 just my notes that I -- and what I was asked was
7 whether I actually brought those points up, and what
8 I'm saying here is I don't recall if I actually brought
9 them up or not.

10 Q. Right.

11 A. That's me, myself, as opposed to someone else
12 at the meeting.

13 Q. Well, you didn't describe them -- nowhere did
14 you suggest that you were writing down what somebody
15 else said, did you? You said, "These are just my
16 thoughts."

17 A. Those three items on the top right-hand corner,
18 correct.

19 Q. As to that part of the document, as to that,
20 you testified those are just my thoughts.

21 A. That's correct.

22 Q. Okay, so, you've told us that at the end of
23 that meeting, the parties agreed that they would
24 consider the matter and talk again.

25 Now, did the Schering-Plough folks call back --

1 call you about two and a half weeks later?

2 A. Yes, we had a conference call.

3 Q. And you made notes of that, didn't you?

4 A. That's right.

5 Q. I think those are at SPX 34, which maybe is the
6 next -- it's a couple of tabs back behind those
7 hard-to-read notes.

8 A. Could you state that SPX number again, please?

9 Q. Sure, it's SPX 34.

10 A. Okay, got it.

11 Q. Have you got it?

12 A. Yep.

13 Q. And are these your notes?

14 A. They are.

15 Q. And were they taken at a conference call with
16 Schering?

17 A. That's right.

18 Q. And it shows the date 4/25/97. Was that the
19 date of the call?

20 A. That's right.

21 Q. And that was about two and a half weeks after
22 the meeting in Miami?

23 A. Yes.

24 Q. April 9th was the other date.

25 A. Yes, okay, yes.

1 MR. NIELDS: Your Honor, I offer this document
2 in evidence.

3 JUDGE CHAPPELL: Objections?

4 MS. APORI: No objection.

5 MR. CURRAN: No objection, Your Honor.

6 JUDGE CHAPPELL: SPX 34?

7 MR. NIELDS: Yes, Your Honor, SPX 34.

8 JUDGE CHAPPELL: Do you want me to rule?

9 MR. NIELDS: Yes, I do.

10 JUDGE CHAPPELL: Okay. Everybody's so eager
11 today.

12 SPX 34 is admitted.

13 (SPX Exhibit Number 34 was admitted into
14 evidence.)

15 MR. NIELDS: Thank you, Your Honor.

16 BY MR. NIELDS:

17 Q. Up at the top it says, "Written offer."

18 Did the Schering folks indicate to you that
19 they were in the process of preparing a written offer?

20 A. Yes.

21 Q. And they wanted to --

22 MR. SILBER: Excuse me, Your Honor, we may have
23 an in camera issue.

24 MR. CAMPBELL: I believe this is in your order,
25 a document that you granted in camera treatment for.

1 MR. NIELDS: Your Honor, Mr. Campbell trumps me
2 once again, and this apparently was ordered to be
3 treated in camera, although for some odd reason, it's
4 shown on our list as not.

5 JUDGE CHAPPELL: So, we've verified that it is
6 in camera, and what's the exhibit number we're
7 referring to?

8 MS. SHORES: It's SPX 34, Your Honor.

9 JUDGE CHAPPELL: Which hasn't been shown yet
10 but you are getting ready to question him about it.

11 MR. NIELDS: Yes. It is going to be oral, Your
12 Honor, but I am going to go into things that are in the
13 document. I don't think I'm going to put it on the
14 ELMO, but I --

15 JUDGE CHAPPELL: Why don't you confer with Mr.
16 Campbell, since he's here, and see if you have any
17 other Kos documents which may or may not be in camera
18 just so we know that. At this time, I'll ask --

19 MR. NIELDS: I'm pretty sure that's -- oh,
20 there is one other -- no, but it's already been used by
21 Ms. Apori, the other one.

22 JUDGE CHAPPELL: Okay. Well, go ahead and
23 confer with him.

24 I am going to have to ask the public to leave
25 the courtroom. We are going into in camera session at

1 this time. You'll be notified when the public may
2 re-enter.

3 (The in camera testimony continued in Volume
4 31, Part 2, Pages 7659 through 7672, then resumed as
5 follows.)

6 JUDGE CHAPPELL: Go ahead.

7 BY MR. NIELDS:

8 Q. Okay, back to the conversation, do you recall
9 Mr. Bell telling Schering that he needed an up-front
10 payment, if Schering wanted to book sales, it needed to
11 pay a premium for that, and that he wanted a sliding
12 scale profit split such that you wouldn't get to 50/50
13 for Schering until a certain sales level had been
14 reached?

15 A. That's correct, those were the points that Dan
16 covered. I don't remember whether the sliding scale
17 discussion was a scale that eventually ended up at 50
18 or started at 50 and went the other way. His main
19 point was that it was a flat concept at the moment, and
20 it needed to have some kind of a variation over time.

21 Q. That would be to Kos' advantage?

22 A. Well, more in keeping with -- that -- that
23 point I think was very dependent on the other points;
24 namely, the up-fronts, et cetera.

25 Q. Now, the proposal that you had gotten was a

1 draft proposal, wasn't it?

2 A. That's right.

3 Q. But it was marked "Draft Proposal."

4 A. Yes.

5 Q. And it had been vetted with you orally before
6 you got it.

7 A. That's right.

8 Q. Did Kos ever make a counterproposal?

9 A. No, Dan -- Dan's remarks basically explained
10 that they need to make a counterproposal or they need
11 to revise their proposal.

12 Q. Did you ever tell Schering or did anybody ever
13 tell Schering that, you know, \$5 million would keep us
14 going or \$10 million or \$15 million or \$20 million?
15 You said that in your direct, but did you ever tell
16 Schering that?

17 A. We never got to numbers, because I think what
18 we needed to first do was to get to the concept, where
19 the up-front payments were something they would
20 willing -- would be willing to entertain, and that
21 wasn't in the written proposal, and that's the point
22 that Dan wanted to drive home.

23 Q. Have you ever -- you've done a lot of
24 negotiations, haven't you, Mr. Patel?

25 A. Yes.

1 Q. Have you ever told a company that you were
2 trying to develop a partnership with that a proposal
3 they had made was insulting?

4 A. Me personally?

5 Q. Yeah.

6 A. I've never used that word.

7 Q. Do you think that would be a good way of
8 inducing the other side to make a cooperative proposal?

9 A. I think when a discussion gets to a
10 negotiation, my philosophy is anything goes.

11 Q. But you've never applied that to yourself;
12 you've never told anybody that their proposal was
13 insulting, have you?

14 A. I personally have not.

15 Q. The concept of an up-front payment in the
16 context of this co-promotion arrangement was not a
17 major issue for all of the people at Kos, was it?

18 A. We all had varying views about the amount.
19 That's why we all -- what we were all agreed on was the
20 concept of an up-front payment.

21 Q. Isn't it true that up-front payments were not a
22 major issue for all the people at Kos?

23 A. I think in a negotiation we all wanted up-front
24 payments. It was a sign of commitment by the big
25 company towards the partnership. Where we may have

1 differed was the amount of the up-fronts and whether
2 the up-fronts could be less if other terms in the
3 arrangement were more generous. So, the whole thing --
4 it's the concept that was important, and it's whether
5 they were interlinked so that one perhaps could be less
6 than the other.

7 Q. Can you turn to page -- it's page -- pages 71,
8 72, 73 and 74 of your -- of your deposition or
9 investigational hearing transcript?

10 A. Seventy?

11 Q. Seventy-one through 74, the four pages on that
12 page.

13 A. Okay.

14 Q. Do you have that in front of you?

15 A. Yes.

16 Q. I'd like you to look at page 73, and you were
17 asked -- at line 9, you were asked this question
18 regarding the proposal that Schering sent:

19 "QUESTION: Okay. Did this proposal include
20 any up front money to Kos?

21 "ANSWER: I'd have to check, but I don't
22 believe so. No.

23 "QUESTION: Was that a matter that was an issue
24 that Kos was unhappy with?

25 "ANSWER: It was certainly an issue with some

1 of us, if not -- it wasn't the major issue for all of
2 us, but it was definitely an issue for those -- and
3 Dan, I know, was not very keen on coming to an
4 agreement if there were no major commitments to up
5 front payments."

6 Did you give that testimony?

7 A. That's right.

8 Q. And was it true that it wasn't -- up-front
9 payments wasn't the major issue for all of the people
10 at Kos?

11 A. That's right.

12 Q. It was a major issue for Mr. Bell, though, yes?

13 A. That's right.

14 Q. And Kos made no counterproposal.

15 A. No.

16 Q. And no deal -- no partnership with Schering was
17 ever consummated.

18 A. That's right.

19 Q. Now, Mr. Patel, you indicated that there were
20 no more communications on this subject. Isn't it true
21 actually that you called Karin Gast personally about
22 two months later and asked her if, you know, there was
23 any chance that Schering might give this some more
24 thought?

25 A. Yes, I had not remembered it earlier on, and I

1 think you reminded me that that is, in fact, what I had
2 done.

3 Q. You were still hoping maybe something could be
4 done?

5 A. Personally, I always hope that something can be
6 done.

7 Q. You mentioned earlier in your testimony the
8 IPO.

9 A. Right.

10 Q. Which I think was in March of '97.

11 A. That's right.

12 Q. Prior to the IPO when you raised money from the
13 stock market, how were the operations of Kos funded?

14 A. By Michael Jaharis' credit line.

15 Q. And about how much money did he put in?

16 A. About \$70 million.

17 Q. And that's not just credit line, is it? He
18 bought stock and put stock -- put money in the company
19 in return for stock, didn't he?

20 A. That's right.

21 Q. And at the time of the IPO, Kos had not had any
22 earnings yet. Is that right?

23 MS. APORI: Objection, Your Honor, this is
24 beyond the scope of the direct.

25 MR. NIELDS: I'm going to get to where it

1 responds to some of the things they did, Your Honor. I
2 can speed this up. I don't have to take huge amounts
3 of time. I will connect it up.

4 JUDGE CHAPPELL: Well, I'll overrule it if I
5 hear a proper foundation. I don't think I heard him
6 tell me how he knows anything about earnings. You
7 asked him about earnings.

8 BY MR. NIELDS:

9 Q. Oh, do you know what the earnings -- do you
10 know whether Kos had earned any money, made any sales
11 prior to the IPO?

12 A. We were in a loss position at the time.

13 Q. About a \$64 million deficit?

14 A. I don't know about that number.

15 Q. Okay. I think you've already testified that --
16 about something a little over \$60 million was raised in
17 the IPO.

18 A. That's right.

19 Q. And that was by selling about 4 million shares
20 for about \$15 a share?

21 A. That's right.

22 Q. And after the IPO, the stock price went up,
23 yes?

24 A. Yes.

25 Q. And eventually it nearly tripled and Kos had a

1 market capitalization of over \$500 million?

2 A. That's right.

3 Q. Towards the summer of '97.

4 A. That's right.

5 JUDGE CHAPPELL: Are you getting to the scope
6 of the direct here?

7 MR. NIELDS: I'm closing in, Your Honor.

8 JUDGE CHAPPELL: Okay.

9 BY MR. NIELDS:

10 Q. Now, market analysts were making projections of
11 Kos' sales, were they not?

12 A. They were.

13 Q. And you were using those in your discussions
14 with possible partners.

15 A. That's right.

16 Q. For example, in your conversations with
17 SmithKline -- I think you testified earlier about your
18 conversations with SmithKline?

19 A. Yes.

20 MS. APORI: Your Honor, at this time I
21 believe --

22 MR. NIELDS: Your Honor, I'm about to go into
23 in camera --

24 JUDGE CHAPPELL: She's first.

25 MS. APORI: I have an objection. I don't think

1 there has been a link established between Kos' IPO and
2 their discussions with SmithKline.

3 MR. NIELDS: Your Honor, their point is that
4 the way -- the way Niaspan did in the U.S. market was
5 irrelevant to any of the potential partners overseas,
6 and I am going to go into a line here which addresses
7 that issue.

8 JUDGE CHAPPELL: I'll allow it as long as I see
9 the connection come out here somewhere. I guess we'll
10 see a lot of this when we review this record. There
11 are a lot of things that are coming in here that are
12 being testified to, but when we all look at this
13 record, some of this is not going to be logical, but go
14 ahead.

15 MR. NIELDS: Thank you, Your Honor.

16 BY MR. NIELDS:

17 Q. I'm going to ask you to look at binder 2. It
18 is a document marked USX 36.

19 MS. APORI: Do we need to go in camera at this
20 point?

21 MR. NIELDS: Yes, I think we do need to go in
22 camera.

23 JUDGE CHAPPELL: I will have to ask the public
24 to leave the courtroom. We are going into in camera
25 session.

1 (The in camera testimony continued in Volume
2 31, Part 2, Pages 7673 through 7686, then resumed as
3 follows.)

4 JUDGE CHAPPELL: Okay, you may proceed.

5 MR. NIELDS: Thank you, Your Honor.

6 BY MR. NIELDS:

7 Q. Now, you also testified about conversations you
8 had with Searle.

9 A. Correct.

10 Q. Do you recall that?

11 A. Yes.

12 Q. By the way, to what do you attribute the low
13 sales results of Kos when you actually went to launch?

14 A. We had 65 to 75 reps launching that product in
15 August-September, and that probably accounts for the
16 low noise level that we had in front of physicians
17 compared to the other big companies.

18 Q. So, if you had had a marketing partner, you
19 think you would have made your projections?

20 A. We would have certainly made the sales numbers
21 or had a better chance of making the sales numbers.

22 Q. Now, you were in negotiations with Searle,
23 correct?

24 A. Yes.

25 Q. And those started sometime in the fall of 1997?

1 A. Yes.

2 Q. And Searle was interested?

3 A. Yes.

4 Q. You had some meetings?

5 A. Yes.

6 Q. Phone calls?

7 A. Yes.

8 Q. You had an exchange of confidentiality
9 agreement in October?

10 A. I believe so.

11 Q. And you were looking for a partner for Niaspan
12 to co-promote in the U.S. Is that right?

13 A. That's correct.

14 Q. In fact, I'm going to ask you to take a look at
15 Exhibit CX 523. Do you have that in front of you?

16 A. Yes.

17 Q. I'm going to read you something, and I'm going
18 to ask you if you recall such a thing. It says,
19 "Kos --" it says, "Mukesh Patel from Kos has called
20 back. Kos indicated they would be prepared to discuss
21 European rights at a later time but that their
22 immediate focus was development and marketing of their
23 product in the short term in the United States. In
24 particular, the possible form of a co-promotion for
25 Niaspan in the United States starting as soon as

1 possible."

2 MS. APORI: Objection, Your Honor, hearsay, and
3 also this document has not been moved into evidence.

4 MR. NIELDS: I'm not going to move it into
5 evidence now, Your Honor. I'm going to ask him whether
6 he recalls having such a conversation.

7 JUDGE CHAPPELL: You're reading from CX 523?
8 Is that what it is, CX 523?

9 MR. NIELDS: Yes, Your Honor.

10 JUDGE CHAPPELL: Which is not admitted?

11 MR. NIELDS: Not admitted.

12 JUDGE CHAPPELL: You are using it to refresh
13 recollection?

14 MR. NIELDS: I'm using it to ask a question on
15 it.

16 JUDGE CHAPPELL: Go ahead. .

17 BY MR. NIELDS:

18 Q. Do you recall having such a conversation with
19 Mr. Egan in early November 1997?

20 A. I remember having many conversations with Jim
21 Egan.

22 Q. Do you remember telling him that Kos would like
23 to talk about European rights later and that you wanted
24 to talk about a co-promotion for Niaspan in the United
25 States as soon as possible?

1 A. That's right.

2 Q. And now, this was nine days before the
3 announcement of the sales results for Kos?

4 A. Yes.

5 Q. And you would have been aware at least in
6 approximate terms of how Kos was doing, yes?

7 A. I'm not sure what you're talking about. Kos as
8 a whole?

9 Q. No, Niaspan, how the Niaspan sales -- it hadn't
10 been public yet, but you had access to the sales
11 numbers, didn't you?

12 A. Yes.

13 Q. So, you knew that in about nine days, the
14 public was going to find out that the sales numbers
15 were pretty disappointing.

16 A. I knew that we were making a quarterly
17 announcement in early November.

18 Q. And you knew that they were -- it was going to
19 be a disappointing announcement.

20 A. I don't -- I didn't know of the details of the
21 announcement, and I had no knowledge of the press
22 release that was going to go out, but I did know how
23 Niaspan was performing in the prior two-three months.

24 Q. And you wanted to find a partner to co-promote
25 Niaspan as quickly as you could, a partner that had

1 real sales muscle, correct?

2 A. I was continuing my co-promotion discussions
3 that year and the following year and the following
4 year. I was always looking for co-promotion partners
5 for this product.

6 Q. Well, what's the answer to my question, though?
7 Were you looking for a -- you knew that the sales
8 performance was disappointing. You attributed it to
9 the fact that you didn't have a partner with a lot of
10 sales muscle, and you were calling Mr. Egan and saying,
11 I want to talk about a co-promote in the U.S. as soon
12 as possible. Are you telling me those things aren't
13 connected?

14 A. To an announcement in the following week
15 regarding sales?

16 Q. Well, let's take it one step at a time. I'm
17 asking you if it -- if the following things are
18 connected: You knew that the sales were very
19 disappointing, you attributed that to the fact that you
20 didn't have a partner, and you were asking Mr. Egan to
21 meet with you as soon as possible to talk co-promotion
22 in the U.S.

23 MS. APORI: Objection, Your Honor, as to the
24 characterization of Mr. Patel's testimony. I don't
25 think that he testified as to those three points.

1 MR. NIELDS: I think he did, Your Honor.

2 JUDGE CHAPPELL: Well, if he didn't, he can
3 tell us in his answer. Overruled.

4 THE WITNESS: I didn't suddenly wake up and
5 realize I needed a co-promotion. This was part of a
6 long-term strategy going back many years and going
7 forward many years to look for a co-promotion partner.
8 The fact that I wanted a discussion with him on this
9 item as well as Europe, in terms of Europe, I wanted a
10 discussion on the U.S. first, and then Europe when it
11 suited him and us.

12 BY MR. NIELDS:

13 Q. And Mr. Egan actually indicated to you, didn't
14 he, that he wanted a guarantee that he would be able to
15 have the European rights, and he wanted that agreed to
16 before he sat down and talked about U.S.?

17 MS. APORI: Objection, Your Honor. Again, I
18 raise the hearsay objection. I don't see what this is
19 going to.

20 MR. NIELDS: Well, it's going to two things,
21 Your Honor. The first is that he's tried to
22 characterize lots of companies he negotiated with as
23 being not interested in Europe. That's point one. I'm
24 rebutting that directly.

25 And second, he has tried to say that there's no

1 connection between the sales results of Niaspan in the
2 U.S. and people's interest in Europe.

3 MS. APORI: Again, I raise the objection,
4 because I feel this is mischaracterizing the testimony.
5 Mr. Patel never testified that there were companies
6 that were not interested in Europe, and I feel that
7 he's offering what Mr. Egan said as to the truth of and
8 not as to the actions.

9 JUDGE CHAPPELL: Is it for the truth?

10 MR. NIELDS: I'm offering it for exactly the
11 same purpose that complaint counsel offered similar
12 conversations.

13 MS. APORI: Your Honor, in our discussion
14 during direct of Mr. Patel's conversations with
15 companies and potential European licensing partners, we
16 did not ask the specific statements from Searle.

17 MR. NIELDS: Well, Your Honor, the answer is
18 I'm not offering it for the truth, and I'm offering it
19 for the same purpose that complaint counsel had offered
20 similar conversations with other companies.

21 JUDGE CHAPPELL: I'll overrule the hearsay
22 objection, then, and also if it's mischaracterizing his
23 testimony, I'll overrule it. The witness can let us
24 know if it does.

25 Susanne, would you read back the question,

1 please.

2 (The record was read as follows:)

3 "QUESTION: And Mr. Egan actually indicated to
4 you, didn't he, that he wanted a guarantee that he
5 would be able to have the European rights, and he
6 wanted that agreed to before he sat down and talked
7 about U.S.?"

8 THE WITNESS: I remember talking to him about
9 having discussions for Europe, because he wanted to
10 have his European colleagues involved in the
11 discussions, and I said -- I recall saying, we're happy
12 to discuss Europe at any time you want, but please
13 let's not forget about what we want to do in the U.S.

14 BY MR. NIELDS:

15 Q. Okay. And then I take it November 12th came
16 and passed and eventually there was no deal with
17 Searle. Is that correct?

18 A. The discussions with Searle went into the first
19 few months in the following year --

20 Q. Well, let's take a look at that. You had a
21 meeting in December, correct?

22 A. In New York?

23 Q. Yes.

24 A. Yes.

25 Q. And if you turn to CX 525, do you see that?

1 A. Yes.

2 Q. That's a letter from you to Mr. Egan? Do you
3 see that?

4 A. Yes.

5 Q. And at the very end of that -- at the top of
6 page 2, it says, "Finally we began exploring the
7 optimum basis for detailing by Kos and Searle. With
8 this in mind, we are preparing a proposal for your
9 consideration."

10 Do you see that?

11 A. Yes.

12 Q. If you turn to the next exhibit, USX 7, and
13 tell us if that's the proposal.

14 This is in camera, Your Honor, USX 7 is in
15 camera.

16 JUDGE CHAPPELL: Okay, we will have to ask the
17 public to leave the courtroom.

18 (The in camera testimony continued in Volume
19 31, Part 2, Pages 7687 through 7689, then resumed as
20 follows.)

21 BY MR. NIELDS:

22 Q. Okay, do you see that, Mr. Patel?

23 A. Yes.

24 Q. Now, my question is Synthelabo, remember you
25 testified about Synthelabo?

1 A. Yes.

2 Q. Is it true that they turned you down after the
3 sales results became public in 1997?

4 A. Yes.

5 Q. And then you testified about Knoll. Is it true
6 that they turned you down during this period of time
7 that's pictured on this chart here?

8 A. Correct.

9 Q. Did you say "correct"?

10 A. Yes.

11 Q. And Pierre Fabre, is it true that they turned
12 you down in this period of time pictured on this chart?

13 A. Yes.

14 Q. And then you testified about Astra. Is it true
15 that they turned you down after the time that's --
16 well, during the time that's pictured on this chart?

17 A. That's right.

18 Q. And Roche, did they turn you down after the
19 time that's pictured on this chart?

20 A. Yes.

21 Q. And we've already established that that was
22 true of SmithKline Beecham. Is that correct?

23 A. Yes.

24 Q. And Searle?

25 A. Yes.

1 Q. And the numbers that are pictured in this chart
2 show sales which are, oh, less than -- in each case
3 less than a fifth of what the market analysts had
4 projected. Is that correct?

5 A. That's right.

6 Q. To your knowledge, does Kos have any patents
7 that have been issued in Europe?

8 A. No issued patents yet.

9 MR. NIELDS: Your Honor, may I have just a
10 moment?

11 JUDGE CHAPPELL: Yes, you may.

12 (Counsel conferring.)

13 MR. NIELDS: I have nothing further, Your
14 Honor.

15 JUDGE CHAPPELL: Any cross from Upsher-Smith?
16 You can finish your powwow if you need to.

17 MR. CURRAN: I think we're all powwowed out,
18 Your Honor.

19 CROSS EXAMINATION

20 BY MR. CURRAN:

21 Q. Hello again, Mr. Patel.

22 A. Hello.

23 Q. Mr. Patel, before the launch of Niaspan, you
24 were looking for a co-promotion partner in the United
25 States, correct?

1 A. Correct.

2 Q. And Schering-Plough was the only company that
3 gave a written proposal during that time frame,
4 correct?

5 A. I believe so.

6 Q. Okay. Sir, during 1997, you were searching for
7 a licensing partner outside the United States, correct?

8 A. We were.

9 Q. And during that time period, you were seeking
10 up-front payments in connection with a licensing
11 transaction, correct?

12 A. We were.

13 Q. Were you trying to defraud the potential
14 licensees?

15 A. No.

16 Q. Was it your belief that Niaspan had value
17 outside the United States?

18 A. Yes.

19 Q. Was it your belief that Niaspan warranted an
20 up-front payment in connection with a licensing
21 transaction outside the United States?

22 A. Yes.

23 MR. CURRAN: Nothing further, Your Honor.

24 MS. APORI: Your Honor, if I may have a minute
25 before redirect?

1 JUDGE CHAPPELL: Yes, you may.

2 (Counsel conferring.)

3 JUDGE CHAPPELL: Go ahead.

4 REDIRECT EXAMINATION

5 BY MS. APORI:

6 Q. Mr. Patel, I'd like to just ask you a few more
7 questions. Can you look to the binder that I provided
8 to you and turn to what's been marked as CX 554?

9 A. Okay.

10 Q. I want you to turn to the third page of that
11 exhibit, AAA 0000155.

12 A. Okay.

13 Q. Okay. And look halfway down the page to the
14 final bullet point, "Sales and Marketing Expenses," and
15 I want to focus on the last sentence underneath that
16 section. "Any differences in costed efforts would
17 become part of quarterly royalty reconciliation."

18 Do you know what that refers to?

19 A. If the amount of expenses contributed by each
20 party was not equal, which was the going-in proposal or
21 the intent, then any difference in the number would be
22 balanced out by adjusting the royalty payments
23 accordingly.

24 Q. So, if Schering contributed more towards the
25 marketing efforts, would Kos have to make up for that

1 extra contribution in a payment to Schering?

2 A. That's right.

3 Q. Mr. Patel, going back to your discussions with
4 potential partners for a European license for Niaspan,
5 did any of your discussions begin after the sales of
6 Niaspan in the United States were available, after
7 November 1997?

8 A. Yes, many discussions.

9 Q. And did any of these companies that you began
10 discussions with after the sales of Niaspan were
11 available in the United States express any concern as
12 to the initial sales of Niaspan?

13 A. I would say their main interest was to learn
14 about the experience that we were gaining in the U.S.
15 and to understand which elements of that experience
16 were relevant to the European marketing experience that
17 we were asking them to review and assess.

18 Q. Did they feel that the sales of Niaspan, that
19 they had not met expectations, were relevant?

20 MR. NIELDS: Objection to what other people
21 felt, Your Honor.

22 JUDGE CHAPPELL: Do you want to rephrase?

23 MS. APORI: I'll rephrase.

24 JUDGE CHAPPELL: Go ahead.

25 BY MS. APORI:

1 Q. Did they express any concerns to you that the
2 sales of Niaspan in the United States were relevant to
3 potential sales in Europe?

4 A. They were always keen on understanding what the
5 sales were in the U.S., but their main focus of
6 interest was what we were doing to promote the product
7 and position the product and at what target physicians
8 we were calling on and which ones we were getting most
9 success from, and on a sales rep -- per -- on a per
10 sales rep basis, we had data that we would show them to
11 show that we were as effective as the competition.

12 Q. So, would you characterize their interest more
13 as to how Kos was launching their efforts to promote
14 Niaspan?

15 MR. NIELDS: Object to this witness
16 characterizing somebody else's interest.

17 MR. CURRAN: And leading, Your Honor.

18 BY MS. APORI:

19 Q. In your discussions, was this issue that was
20 raised by you, this issue being how Kos was promoting
21 Niaspan in the United States, did you ever raise that
22 as an issue in your discussions with European
23 companies?

24 A. The main focus of our discussions with European
25 companies was to give them as much understanding of how

1 we were marketing the product, and that was the main
2 interest that they had.

3 MS. APORI: Thank you, Mr. Patel.

4 JUDGE CHAPPELL: Are you finished?

5 MS. APORI: No further questions.

6 JUDGE CHAPPELL: Okay. Any further questions
7 of this witness?

8 MR. NIELDS: No, Your Honor.

9 MR. CURRAN: No, Your Honor.

10 JUDGE CHAPPELL: Thank you, Mr. Patel, you're
11 excused.

12 Ms. Bokat, do we have a full day of testimony
13 tomorrow?

14 MS. BOKAT: Thank you for the opportunity, Your
15 Honor. We have a schedule change tomorrow. You'll
16 recall at the end of the day yesterday there was some
17 discussion about Michael Valazza at IPC and whether we
18 were going to be able to speak to him before he went on
19 the stand, which was proposed for tomorrow morning.

20 Upsher-Smith suggested that we could talk to
21 Mr. Valazza before he went on. We sought some
22 clarification after the Court ended the day yesterday,
23 and apparently the parameters of what we could talk to
24 him about were to exclude anything about Upsher-Smith's
25 business, which was the relevance of his testimony.

1 I conferred with counsel for IPC last night to
2 see if that was their understanding, and it was also
3 their understanding that the FTC was not at liberty to
4 talk to IPC about Upsher's business. So, based on
5 that, we have elected not to call Mr. Valazza.

6 The witness we planned for tomorrow afternoon,
7 Professor Adelman, is -- we did some shuffling. He is
8 coming in from Michigan and changed his plane flight so
9 that he can be here at 10:30 tomorrow morning. Perhaps
10 one thing we could take up before he goes on the stand
11 would be the remaining issues as to the Schering
12 exhibits that were deferred to allow us to put Mr.
13 Patel on today. So, perhaps we could do that at the
14 beginning of the session tomorrow if that's the Court's
15 pleasure.

16 JUDGE CHAPPELL: We only have one witness
17 tomorrow?

18 MS. BOKAT: That's right.

19 JUDGE CHAPPELL: How long is your anticipated
20 direct examination?

21 MS. BOKAT: I don't know. I am not doing the
22 examination of Professor Adelman.

23 JUDGE CHAPPELL: Mr. Nolan?

24 MS. BOKAT: I believe Ms. Michel is doing the
25 direct examination of Professor Adelman.

1 JUDGE CHAPPELL: One of the patent people?

2 MS. BOKAT: Yes, he's a patent lawyer, Your
3 Honor.

4 JUDGE CHAPPELL: I realize when I come in here
5 I can look behind the tables and know what kind of
6 witness is going to take the stand.

7 It sounds like we'll have plenty of time to
8 handle the exhibits tomorrow after Mr. Adelman
9 testifies. I've got a few things I'm trying to wrap up
10 and could use an hour or two in the morning, so why
11 don't we start at 10:30 tomorrow.

12 MS. BOKAT: That's fine, Your Honor.

13 JUDGE CHAPPELL: Okay.

14 MS. SHORES: Thank you, Your Honor, that's
15 fine.

16 MR. CURRAN: No problem, Your Honor, thank you.

17 JUDGE CHAPPELL: So, we will adjourn until
18 10:30 in the morning.

19 (Whereupon, at 5:45 p.m., the hearing was
20 adjourned.)

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1 C E R T I F I C A T I O N O F R E P O R T E R

2 DOCKET/FILE NUMBER: 9297

3 CASE TITLE: SCHERING-PLOUGH/UPSHER-SMITH

4 DATE: MARCH 13, 2002

5

6 I HEREBY CERTIFY that the transcript contained
7 herein is a full and accurate transcript of the notes
8 taken by me at the hearing on the above cause before
9 the FEDERAL TRADE COMMISSION to the best of my
10 knowledge and belief.

11

12 DATED: 3/14/02

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14

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16 SUSANNE BERGLING, RMR

17

18 C E R T I F I C A T I O N O F P R O O F R E A D E R

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20 I HEREBY CERTIFY that I proofread the
21 transcript for accuracy in spelling, hyphenation,
22 punctuation and format.

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